FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

Selection Criteria:

Product Name:	.;LEXAPRO
Product Active Ingredient:	·
Active Ingredient	·
Active Moiety:	·
FDA Received Date:	From: 05-DEC-2008 To: 05-DEC-2013
MedDRA® Version* :	16.1
Total Cases**:	2,277
Number of Pages:	951

Disclaimer: Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

*. “MedDRA® Version” refers to the name and version of the dictionary in use at the time the cases were retrieved from the FDA Adverse Event Reporting System (FAERS). MedDRA Medical Dictionary for Regulatory Activities (MedDRA®) is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to code adverse events, medication errors and other information associated with the use of medical products. A MedDRA® Preferred Term (PT) is used to standardize a “medical concept” in a report. For example, a report of “heart attack” or “myocardial infarct” are standardized to the same Preferred Term, “Myocardial Infarction”. MedDRA is updated twice a year.

**. “Total Cases” reflects the number of individual patient case reports associated with the product of interest that were submitted to FDA within the specified time period. A case consists of an initial report and any follow-up reports submitted to FDA. Because FDA may receive reports on the same patient from more than one source, some of these cases may be duplicate patient reports.

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The information in this report is generated from the FDA Adverse Event Reporting System (FAERS) by using a report query where suspect product(s) or active ingredients are selected from a standardized dictionary and a date range is specified as search criteria. The table below provides the definitions for field headings that are listed on the report.

FAERS data have limitations, including the following. There is no certainty that the reported event was actually due to the product. Reports are often incomplete - a blank field means that no data were provided. FDA does not receive reports on all adverse events that occur with a product. Many factors can influence whether or not an event will be reported, therefore, FAERS data cannot be used to compare products or calculate how frequently an event occurs in the U.S. population.

Field Heading	Definition
FDA Received Date	The date that FDA received the most recent information regarding a case, either as an initial report or follow-up report. The FDA Received Date may not be the same as the date that the event occurred. The event may have occurred days or even months (or years) before the report was sent to (and received by) FDA. Note the displayed date on the report may be later than the query date range if FDA received follow-up information for a case. FDA provides the most current case information available.
Case #	A unique number assigned by FDA that identifies a FAERS case. A case includes the information received in the initial report plus any additional information received in follow-up reports.
Case Type	There are three case types in FAERS: Expedited (15-Day): submitted to FDA by manufacturers; these are reports containing serious, unexpected adverse events Nonexpedited: submitted periodically to FDA by manufacturers; these are reports containing adverse events other than those qualifying for expedited (15-day) reporting Direct: submitted “directly” to FDA by healthcare professionals, patients and other consumers
Health Professional	Indicates whether the initial source who provided information about the event is a health professional (HP). Possible values are; Y - Yes, N – No or the field is blank if it was not reported
Outcomes	Based on FDA regulations, the reported outcome(s) determines whether a case is serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OT), and required intervention to prevent permanent impairment/damage (RI). A case can have more than one outcome.
Manufacturer Control #	The Manufacturer Control Number is the manufacturer’s unique identifier associated with the case. Also referred to as the Company Report Number.
Age	The patient's age, with age unit, based on information provided in the report.
Sex	Patient sex (Male, Female, Unknown).
Country	The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.

Field Heading	Definition
Preferred Term	A Medical Dictionary for Regulatory Activities (MedDRA®) Preferred Term (PT) is used to standardize a “medical concept” in a report. For example, a report of “heart attack” or “myocardial infarct” are standardized to the same Preferred Term, “Myocardial Infarction”. MedDRA is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to “code” adverse events, medication errors and other information associated with the use of medical products
Product	Name of a drug or therapeutic biologic in the case report. A product name can appear as either a brand name (trade name) or an active ingredient name, depending on what was reported.
Role	There are two roles for products listed on the cases. Suspect (S) identifies the product(s) that the initial reporter deemed most likely to be associated with the event. Concomitant (C) identifies products taken at the same time as the suspect product, but not deemed by the initial reporter as being associated with the event.
Route	Reported route of product administration (e.g., oral, topical, injection, sublingual, inhalation).
Dosage Text	Refers to the amount of the product that was taken or given to a patient, and the frequency of administration. For example, 20 mg twice daily.
Duration	The length of time the product was used. For example, if someone reported taking Drug A from January 1 to January 30, the duration would be 30 days.
Manufacturer	The manufacturer of the product, as indicated in the report.

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Dec-2008	6835614	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20081201102	27 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	FLEXERIL	S		50-60 mg once		
DRUG INTERACTION	LEXAPRO	S				
INTENTIONAL OVERDOSE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Dec-2008	6841907	NON-EXPEDITED	N		US-AMGEN-KDL274198	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH PRURITIC	ENBREL	S	SUBCUTANEOUS			
RASH ERYTHEMATOUS	ENBREL	S				
	UNSPECIFIED INGREDIENT	S				
	LEXAPRO	S				
	TRICOR	S				
	VERAPAMIL HYDROCHLORIDE	S				
	PLAVIX	S				
	NIACIN	S				
	MAGNESIUM OXIDE	S				
	UNSPECIFIED INGREDIENT	S				
	CRESTOR	S				
	FLOMAX	S				
	SINGULAIR	S				
	ZETIA	S				
	PROTONIX	S				
	SYMLIN	S				
	SYNTHROID	S				
	TOPAMAX	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Dec-2008	6773930	EXPEDITED (15-DAY)	Y	OT	1000000944	53 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GRAND MAL CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG 1 IN 1 D), ORAL		
FALL	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL		
ANXIETY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Dec-2008	6866136	EXPEDITED (15-DAY)	Y	OT	1000003117		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	ORAL		
	ULTRAM	S	ORAL	300 MG (300 MG, 1 IN 1 D), ORAL		
	FLEXERIL	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2008	6866552	EXPEDITED (15-DAY)	N	HO	1000003130	18 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONTUSION	LEXAPRO	S		ORAL		
INTENTIONAL SELF-INJURY	WELLBUTRIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2008	6867086	EXPEDITED (15-DAY)	Y	OT	1000003121	69 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DELIRIUM	LEXAPRO	S				
DRUG INTERACTION	TACROLIMUS	S				
HALLUCINATION	PROPOXYPHENE HYDROCHLORIDE	C				
DISORIENTATION	PROMETHAZINE	C				
CONFUSIONAL STATE	LANSOPRAZOLE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2008	6853975	EXPEDITED (15-DAY)	N	OT	A0760418A		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGGRESSION	DEXEDRINE	S	UNKNOWN			GLAXOSMITHKLINE
SOMNOLENCE	LEXAPRO	S	UNKNOWN			
	KLONOPIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Dec-2008	6803782	EXPEDITED (15-DAY)	N	DE	1000001403	24 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S				
HOMICIDE	RISPERDAL	C				
ABNORMAL BEHAVIOUR						
BRAIN CONTUSION						
COMPLETED SUICIDE						
GUN SHOT WOUND						
LEFT VENTRICULAR HYPERTROPHY						
PULMONARY HAEMORRHAGE						
SUBARACHNOID HAEMORRHAGE						
TREATMENT NONCOMPLIANCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2008	6820487	EXPEDITED (15-DAY)	N	DE	US-BRISTOL-MYERS SQUIBB COMPANY-14414346	30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEATH	ABILIFY	S	ORAL	Start date of treatment:over a year ago.		
	ABILIFY	S	ORAL	Start date of treatment:over a year ago.		
	ABILIFY	S	ORAL	Start date of treatment:over a year ago.		
	ABILIFY	S	ORAL	Start date of treatment:over a year ago.		
	LEXAPRO	S				
	LEXAPRO	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2008	6860212	NON-EXPEDITED	N		US-ASTRAZENECA-2008UW23143	66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALOPECIA	CRESTOR	S	ORAL			
	LEXAPRO	S	ORAL		12 MTH	
	LEXAPRO	S	ORAL		12 MTH	
	SYNTHROID	S	ORAL		15 YR	
	SYNTHROID	S	ORAL	100MCG DAILY		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2008	6870631	DIRECT	Y			50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GASTROINTESTINAL HAEMORRHAGE	LEXAPRO	S		ONE TO TWO TABLETS DAILY	1 YR	FOREST
DRUG INTERACTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Dec-2008	6871516	DIRECT	N	DE		48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	OTHER	10 MG TABLET 1 TABLET EVERY MOR OTHER		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Dec-2008	8268283	EXPEDITED (15-DAY)	N	OT	US-KINGPHARMUSA00001-K200801406	38 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANIC ATTACK	SKELAXIN	S		UNK		KING
DRUG INTERACTION	ALLEGRA D-12 HOUR	S		UNK		
HEART RATE INCREASED	LEXAPRO	S	ORAL	10 mg, qd	1 DAY	
PARAESTHESIA	LEXAPRO	S	ORAL	5 mg, qd	2 DAY	
HYPOAESTHESIA	UNSPECIFIED INGREDIENT	S		UNK		
MYDRIASIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Dec-2008	6871837	DIRECT		HO,OT		20 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MENTAL DISORDER	LEXAPRO	S	ORAL	20 MG 2 PILLS ONCE A DAY PO		
HOSTILITY	WELLBUTRIN	S	ORAL	300 MG PO		
ABDOMINAL PAIN						
ANGER						
CONDITION AGGRAVATED						
CONFUSIONAL STATE						
CONTUSION						
DEPRESSION						
DIABETES MELLITUS						
DRY MOUTH						
EYE IRRITATION						
FACIAL PAIN						
HEADACHE						
HYPERPHAGIA						
HYPOPHAGIA						
NASAL DISCOMFORT						
SINUS DISORDER						
TREMOR						
URINE FLOW DECREASED						
VISION BLURRED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Dec-2008	6786190	NON-EXPEDITED	Y	OT	US-WYE-H05280808	17 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PALPITATIONS	PRISTIQ EXTENDED RELEASE	S	ORAL	50 MG 1X PER 1 DAY, ORAL		
	LEXAPRO	S		25 MG 1X PER 1 DAY		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Dec-2008	6823221	EXPEDITED (15-DAY)	Y	HO	1000001683	83 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GASTRIC ULCER	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ANAEMIA	COUMADIN	S	ORAL	(2.5 MG), ORAL		
UPPER GASTROINTESTINAL HAEMORRHAGE	TORSEMIDE (10 MILLIGRAM)	C				
INTERNATIONAL NORMALISED RATIO INCREASED	NADOLOL (20 MILLIGRAM)	C				
WHITE BLOOD CELL COUNT INCREASED	POTASSIUM (10 MILLIEQUIVALENTS)	C				
DIZZINESS	CLONIDINE (0.1 MILLIGRAM)	C				
	MECLIZINE	C				
	MONOPRIL	C				
	NEURONTIN	C				
	VITAMINS (NOS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2008	6871818	EXPEDITED (15-DAY)	Y	DE	1000003238		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEATH	LEXAPRO	S				
	ATIVAN	S				
	ALCOHOL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2008	6871824	EXPEDITED (15-DAY)	N	DE	1000003193		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2008	6872214	DIRECT	N	HO,OT		36 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	LEXAPRO	S	ORAL	1 DOSE/ 10MG 1 TIME PO		
ANXIETY						
Coordination abnormal						
DIPLOPIA						
DYSPNOEA						
FEELING COLD						
HEADACHE						
HOT FLUSH						
MUSCULAR WEAKNESS						
PALPITATIONS						
TREMOR						
VERTIGO						
VISION BLURRED						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Dec-2008	6874024	EXPEDITED (15-DAY)	Y	HO	1000003233	22 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
DEPRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Dec-2008	6878362	EXPEDITED (15-DAY)	Y	CA	1000003244		Unknown	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MATERNAL EXPOSURE DURING PREGNANCY	LEXAPRO	S	TRANSPLACENTAL	TRANPLACENTAL		
CLEFT PALATE						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Dec-2008	6873658	DIRECT	N			18 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING ABNORMAL	LEXAPRO	S	ORAL	10 MG DAY PO		
ANHEDONIA						
DEHYDRATION						
HUNGER						
HYPERHIDROSIS						
LOSS OF LIBIDO						
PAIN						
THIRST						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Dec-2008	6874652	DIRECT	N	DE		49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S		10MG DAILY		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Dec-2008	6874865	DIRECT	Y	HO,LT		75 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NODAL ARRHYTHMIA	LEXAPRO	S	ORAL	MG QDAY PO		
ASTHENIA	TRAMADOL HYDROCHLORIDE	C				
FATIGUE	PROTONIX	C				
NAUSEA	LYRICA	C				
VOMITING	CARBO LEVODOPA	C				
PRESYNCOPE	LEXAPRO	C				
	VITAMIN D	C				
	OXCARBAZEPINE	C				
	DIAZEPAM	C				
	ASA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Dec-2008	6875063	DIRECT	N	DE		46 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEATH	CYMBALTA	S				
	LEXAPRO	S				
	EFFEXOR XR	S		37.5 - 75 MG.		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Dec-2008	6876621	EXPEDITED (15-DAY)	N	OT	1000003317		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL		
LETHARGY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Dec-2008	6879835	EXPEDITED (15-DAY)	Y	DE	1000003265	48 YR	Male	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Dec-2008	6878072	DIRECT	N	RI		27 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PARAESTHESIA	LEXAPRO	S	ORAL	1 ONCE A DAY PO		
ANORGASMIA						
DISTURBANCE IN SEXUAL AROUSAL						
SEXUAL DYSFUNCTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2009	6914785	DIRECT	N	HO,LT,OT		15 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	ZOLOFT	S	ORAL	LOW DOSAGE - DON'T REMEMBER DAILY PO		
CONDITION AGGRAVATED	LEXAPRO	S	ORAL	LOW DOSAGE - DON'T REMEMBER DAILY PO		
SUICIDAL BEHAVIOUR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jan-2009	6879183	DIRECT		DE,DS,LT		46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NO ADVERSE EVENT	LEXAPRO	S				
	CYMBALTA	S				
	EFFEXOR XR	S		75MG. INTERNAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jan-2009	6879191	DIRECT	N	DS,OT,RI		29 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEXUAL ABUSE	AMBIEN	S		VARIOUS DAILY		
AMNESIA	TRAZODONE HYDROCHLORIDE	S		VARIOUS DAILY		
IMPRISONMENT	TEMAZEPAM	S		VARIOUS DAILY		
	PAXIL	S		VARIOUS DAILY		
	CELEXA	S		VARIOUS DAILY		
	RESTORIL	S		VARIOUS DAILY		
	LEXAPRO	S		VARIOUS DAILY		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jan-2009	6879993	EXPEDITED (15-DAY)	Y	CA	1000003363		Unknown	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PYELOCALIECTASIS	LEXAPRO	S	TRANSPLACENTAL	(20 MG), TRANSPLACENTAL		
Maternal drugs affecting foetus						
NEONATAL DISORDER						
URETERIC OBSTRUCTION						
VESICOURETERIC REFLUX						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jan-2009	6887386	DIRECT	Y	OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEADACHE	BUPROPION	S	ORAL	150 MG ONCE QD PO		
DIZZINESS	LEXAPRO	S	ORAL	10 MG ONCE PO QD		
FEELING ABNORMAL						
GASTRIC DISORDER						
NAUSEA						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jan-2009	6862740	EXPEDITED (15-DAY)	Y	HO,DS	1000003070	26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GRAND MAL CONVULSION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
AMNESIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
TREMOR	FLEXERIL	C				
ARTIFICIAL MENOPAUSE						
HAND FRACTURE						
PREMATURE MENOPAUSE						
Spinal fracture						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jan-2009	6881075	EXPEDITED (15-DAY)	Y	DE	DSA_32973_2009		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEATH	ATIVAN	S		DF		
	LEXAPRO	S		DF		
	ALCOHOL	S		DF		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jan-2009	6881191	EXPEDITED (15-DAY)	N	HO,OT	1000003414	39 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALCOHOL POISONING	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
HERPES ZOSTER	ALCOHOL	S	ORAL	ORAL		
IMPRISONMENT						
Scar						
TRIGEMINAL NERVE DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2009	6722037	EXPEDITED (15-DAY)	Y	HO	1000000179	17 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRIAPISM	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
NO THERAPEUTIC RESPONSE	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
	RISPERDAL	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2009	6878445	EXPEDITED (15-DAY)	N	OT	A0762895A	26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	BUPROPION	S	ORAL	150MG Per day		GLAXOSMITHKLINE
TREMOR	HUMIRA	S	SUBCUTANEOUS			
ASTHENIA	VICODIN	S	ORAL	3TAB per day		
DRUG INTERACTION	LEXAPRO	S	ORAL	20MG Per day		
WITHDRAWAL SYNDROME	CHLORMEZANONE	S				
FEELING ABNORMAL	AMITRIPTYLINE	S	ORAL	75MG At night		
CONFUSIONAL STATE	RIZATRIPTAN BENZOATE	S	ORAL	10MG Per day		
DIZZINESS	PREGABALIN	S	ORAL	50MG Twice per day		
PAIN IN EXTREMITY	CELECOXIB	S	ORAL	200MG Per day		
LIMB INJURY	CYCLOBENZAPRINE HYDROCHLORIDE	S	ORAL	10MG Three times per day		
LOCALISED INFECTION	UNSPECIFIED INGREDIENT	S	ORAL	100MG Twice per day		GLAXOSMITHKLINE
AMNESIA	CLINDAMYCIN	S	ORAL	100MG Three times per day	7 DAY	
	TETANUS TOXOID NOS	S	INTRAMUSCULAR			GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jan-2009	6879194	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20090101314	26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	CYCLOBENZAPRINE HYDROCHLORIDE	S	ORAL	as needed		
DRUG INTERACTION	HUMIRA	S		40mg/0.8ml		
ASTHENIA	VICODIN	S		5/500, 3 times daily, as needed		
TREMOR	LEXAPRO	S	ORAL			
PAIN IN EXTREMITY	CHLORMEZANONE	S	ORAL			
	AMITRIPTYLINE HYDROCHLORIDE	S	ORAL			
	RIZATRIPTAN BENZOATE	S	ORAL			
	PREGABALIN	S	ORAL			
	CELECOXIB	S	ORAL			
	BUPROPION	S	ORAL			
	MINOCYCLINE HYDROCHLORIDE	S	ORAL			
	CLINDAMYCIN	S	ORAL			
	TETANUS TOXOID NOS	S	INTRAMUSCULAR			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jan-2009	6889849	DIRECT	N			41 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
URINARY RETENTION	LEXAPRO	S	ORAL	10 MG DAILY PO	5 YR	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2009	6891256	DIRECT	N	OT		26 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	LEXAPRO	S		DAILY		
MENTAL DISORDER	EFFEXOR XR	S		DAILY		
FEELING ABNORMAL	LAMICTAL	S		DAILY		
PAIN	CELEXA	S		DAILY		
PRURITUS	REMERON	S		DAILY		
BURNING SENSATION						
FEELING HOT						
PARAESTHESIA						
SENSORY DISTURBANCE						
SHOCK						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jan-2009	6881983	NON-EXPEDITED	N		US-BAYER-200814635BCC	23 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MENTAL DISORDER	ALEVE	S	ORAL			BAYER
DECREASED APPETITE	LEXAPRO	S	ORAL	Total daily dose: 20 MG Unit dose: 20 MG		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jan-2009	6888270	EXPEDITED (15-DAY)	N	OT	S08-USA-01768-01	30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PREGNANCY	LEXAPRO	S	ORAL	1 IN 1 D, ORAL; 20 MG (20 MG, 1 IN 1 D), ORAL ; 10 MG, (10 MG, 1 IN 1 D), ORAL		
POSTPARTUM HAEMORRHAGE	XANAX (ALPRAZOLAM) (ALPRAZOLAM)	C				
DEPRESSION						
MATERNAL EXPOSURE DURING PREGNANCY						
MOOD SWINGS						
PARAESTHESIA						
PARANOIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2009	6883336	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14013106		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	ABILIFY	S				
URINE ODOUR ABNORMAL	PROVIGIL	S	ORAL			
DRUG SCREEN POSITIVE	KEPPRA	S				
	LEXAPRO	S				
	LAMICTAL	S				
	LEVOTHYROXINE	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2009	6884386	NON-EXPEDITED	Y		PR-BRISTOL-MYERS SQUIBB COMPANY-14327126		Female	PRI

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	ABILIFY	S		1/2 tablet,as Adjunctive therapy		
	ABILIFY	S		1/2 tablet,as Adjunctive therapy		
	LEXAPRO	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2009	6884426	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14336150	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	ABILIFY	S		Began 1 1/2 years ago, stopped and restarted 2 times		
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2009	6884530	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-14351779	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GALACTORRHOEA	ABILIFY	S		Dose reduced to 2.5 mg and was possibly withdrawn.	20 MTH	
HYPERPROLACTINAEMIA	FLUOXETINE	S				
	LEXAPRO	S				
	CYMBALTA	S				
	STRATTERA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2009	6884598	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-14362313		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	ABILIFY	S				
RESTLESSNESS	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2009	6884662	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-14369326	17 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	ABILIFY	S		interrupted & restarted on 7Oct08. 1/2 tab on day 1 and 1/2 tab on day 2. then discontinued.		
FEELING JITTERY	ABILIFY	S		interrupted & restarted on 7Oct08. 1/2 tab on day 1 and 1/2 tab on day 2. then discontinued.		
CRYING	ABILIFY	S		interrupted & restarted on 7Oct08. 1/2 tab on day 1 and 1/2 tab on day 2. then discontinued.		
AGGRESSION	TOPAMAX	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2009	6884786	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14382543		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2009	6892706	EXPEDITED (15-DAY)	N	OT	S08-USA-01838-01	31 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PREGNANCY	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D) ,ORAL; 20 MG (20 MG, 1 IN 1 D) ,ORAL		
CONTUSION						
DIARRHOEA						
DIZZINESS						
MATERNAL EXPOSURE DURING PREGNANCY						
NAUSEA						
VAGINAL HAEMORRHAGE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jan-2009	6821501	EXPEDITED (15-DAY)	Y	OT	1000001582	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEADACHE	LEXAPRO	S	ORAL	ORAL		
INSOMNIA	XANAX	S				
SCREAMING	ZOLOFT	S				
PAIN	NEURONTIN	S				
SLEEP APNOEA SYNDROME	TRAZODONE HYDROCHLORIDE	S				
NIGHTMARE	SEROQUEL	S				
DEPRESSION	WELLBUTRIN	S				
PANIC ATTACK	RESTORIL	S				
ANGER	CYMBALTA	S				
MENTAL DISORDER	EFFEXOR	S				
AMNESIA	FENOFIBRATE	C				
BACK PAIN	LEVOTHYROXINE	C				
CONSTIPATION	AMBIEN	C				
DECREASED APPETITE	HYDROCHLOROTHIAZIDE	C				
ASBESTOSIS	HYDROCODONE BITARTRATE & ACETAMINOPHEN	C				

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PALLOR	CARISOPRODOL	C				
ACTIVITIES OF DAILY LIVING IMPAIRED	LISINOPRIL	C				
ABNORMAL BEHAVIOUR						
ANXIETY						
APHASIA						
ATTENTION DEFICIT/HYPERACTIVITY DISORDER						
BLOOD CHOLESTEROL INCREASED						
BLOOD TRIGLYCERIDES ABNORMAL						
BRUXISM						
CONDITION AGGRAVATED						
CONVULSION						
DIALYSIS						
EMOTIONAL DISTRESS						
FEELING ABNORMAL						
HALLUCINATION						
HYPERHIDROSIS						
HYPERTENSION						
HYPOPHAGIA						
HYPOTHYROIDISM						
INCORRECT DOSE ADMINISTERED						
LETHARGY						
MUSCLE SPASMS						
MUSCLE TWITCHING						
NIGHT SWEATS						
PANCREATITIS						
PARANOIA						
RENAL FAILURE						
RESTLESS LEGS SYNDROME						
ROAD TRAFFIC ACCIDENT						
SEDATION						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SOCIAL AVOIDANT BEHAVIOUR						
SUICIDAL IDEATION						
SUICIDE ATTEMPT						
TACHYCARDIA						
TARDIVE DYSKINESIA						
TERMINAL INSOMNIA						
THYROID DISORDER						
TREATMENT NONCOMPLIANCE						
TREMOR						
URINARY INCONTINENCE						
VOMITING						
WEIGHT DECREASED						
WITHDRAWAL SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jan-2009	6895646	DIRECT	N	DE		77 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	10MG THEN UPPED TO 20MG ONCE A DAY PO		
CONDITION AGGRAVATED	TRAZODONE HYDROCHLORIDE	S	ORAL	100MG- 1 D PO		
	AMBIEN CR	S	ORAL	L N PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jan-2009	6896501	EXPEDITED (15-DAY)	N	OT	1000003471		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FOETAL HEART RATE DECREASED	LEXAPRO	S	TRANSPLACENTAL	10 MG (10 MG, 1 IN 1 D), TRANSPLACENTAL; 20 MG (20 MG, 1 IN 1 D),TRANSPLACENTAL		

Maternal drugs affecting foetus

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2009	6862637	EXPEDITED (15-DAY)	N	HO,LT	BR-GENENTECH-273165	49 YR	Female	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ASTHMA	XOLAIR	S	SUBCUTANEOUS	300 mg, 2/week		GENENTECH
	XOLAIR	S	SUBCUTANEOUS	UNK		GENENTECH
	LEXAPRO	S				
	FORASEQ (BRAZIL)	C				
	SPIRIVA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2009	6901541	EXPEDITED (15-DAY)	Y	DE	1000003591	38 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D) ,ORAL		
	XANAX	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2009	6858753	EXPEDITED (15-DAY)	Y	HO,OT	1000003005	66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cervical vertebral fracture	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL, 20 MG (20 MG, 1 IN 1 D), ORAL		
FALL	LEXAPRO	S	ORAL	SEE IMAGE		
THROMBOCYTOPENIA	XANAX	S	ORAL	0.5 MG (0.5 MG, AS REQUIRED), ORAL		
CONDITION AGGRAVATED	LISINOPRIL	C				
TYPE 2 DIABETES MELLITUS	PROTONIX	C				
VIOLENCE-RELATED SYMPTOM	NORVASC	C				
AGGRESSION	CINNAMON	C				
AGITATION	CARAFATE	C				
ANXIETY	MIRALAX	C				
SEDATION						
SOMNOLENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2009	6902819	DIRECT	N	RI		26 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LIBIDO DECREASED	LEXAPRO	S	ORAL	10MG 1 DAILY PO	3 DAY	
ANAESTHESIA						
ANHEDONIA						
ANORGASMIA						
CONDITION AGGRAVATED						
DEPRESSION						
EJACULATION DELAYED						
EJACULATION DISORDER						
GENITAL DISORDER MALE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2009	6575575	EXPEDITED (15-DAY)	Y	DE,CA	S08-USA-00471-02		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CLEFT PALATE	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
SKULL MALFORMATION	REBIF	S	TRANSPLACENTAL	44 MCG, THREE TIMES PER WEEK, TRANSPLACENTAL		
STILLBIRTH	NEURONTIN	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus	MECLIZINE	S	TRANSPLACENTAL	TRANSPLACENTAL		
LIMB REDUCTION DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2009	6894705	EXPEDITED (15-DAY)	N	OT	AU-SANOFI-SYNTHELABO-A01200900474		Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CEREBROVASCULAR ACCIDENT	LEXAPRO	S	ORAL			
AMNESIA	ZOLPIDEM	S	ORAL	UNK		
INAPPROPRIATE SCHEDULE OF DRUG ADMINISTRATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2009	6895684	NON-EXPEDITED	N		A0702781A	33 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANGER	WELLBUTRIN	S				GLAXOSMITHKLINE
PSYCHOMOTOR HYPERACTIVITY	LEXAPRO	S	UNKNOWN			
DRUG INTERACTION	AMBIEN	S	UNKNOWN			
	UNSPECIFIED INGREDIENT	S	UNKNOWN			GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2009	6895756	NON-EXPEDITED	N		A0729964A	38 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEADACHE	WELLBUTRIN	S	ORAL	75MG Three times per day		GLAXOSMITHKLINE
APHTHOUS STOMATITIS	LEXAPRO	S		10MG Per day		
GLOSSITIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2009	6905821	EXPEDITED (15-DAY)	Y	OT	1000003652		Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERACUSIS	LEXAPRO	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2009	6897054	EXPEDITED (15-DAY)	N	OT	US-MERCK-0901USA01520	23 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	MAXALT	S	ORAL			MERCK
DRUG INTERACTION	FLEXERIL	S	ORAL			
ASTHENIA	HUMIRA	S	UNKNOWN			
PAIN IN EXTREMITY	VICODIN	S	ORAL			
TREMOR	LEXAPRO	S	ORAL			
WITHDRAWAL SYNDROME	CHLORMEZANONE	S	ORAL			
CONFUSIONAL STATE	ELAVIL	S	ORAL			
DIZZINESS	PREGABALIN	S	ORAL			
LOCALISED INFECTION	CELECOXIB	S	ORAL			
LIMB INJURY	BUPROPION HYDROCHLORIDE	S	ORAL			
FEELING ABNORMAL	MINOCYCLINE	S	ORAL			
	CLINDAMYCIN	S	ORAL			
	TETANUS TOXOID NOS	S	INTRAMUSCULAR			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2009	6907558	EXPEDITED (15-DAY)	Y	DE	1000003683		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2009	6899800	EXPEDITED (15-DAY)	N	OT	US-WYE-H07876809	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	EFFEXOR	S	ORAL	unknown		WYETH
FEELING ABNORMAL	LEXAPRO	S	ORAL	unknown		LUNDBECK
DISORIENTATION	LEXAPRO	S				LUNDBECK
AMNESIA	XANAX	S		unknown		
ABNORMAL BEHAVIOUR	XANAX	S				
ROAD TRAFFIC ACCIDENT	XANAX	S				
TARDIVE DYSKINESIA	ZOLOFT	S		unknown		PFIZER
BRUXISM	NEURONTIN	S		unknown		
SOCIAL AVOIDANT BEHAVIOUR	NEURONTIN	S				
SEDATION	TRAZODONE HYDROCHLORIDE	S		unknown		UNKNOWN
PANIC REACTION	SEROQUEL	S		unknown		UNKNOWN
ANGER	SEROQUEL	S				UNKNOWN
MENTAL DISORDER	WELLBUTRIN	S		unknown		GLAXOSMITHKLINE
INTENTIONAL OVERDOSE	WELLBUTRIN	S				GLAXOSMITHKLINE
SUICIDAL IDEATION	RESTORIL	S		unknown		
HALLUCINATION	CYMBALTA	S		unknown		ELI LILLY AND CO
SCREAMING	LEVOTHYROXINE	C				UNKNOWN
NIGHTMARE	AMBIEN	C				
INSOMNIA	HYDROCHLOROTHIAZIDE	C				UNKNOWN
PYREXIA	HYDROCODONE BITARTRATE & ACETAMINOPHEN	C				
HYPERHIDROSIS	CARISOPRODOL	C				UNKNOWN
NIGHT SWEATS	LISINOPRIL	C				UNKNOWN
PARANOIA	FENOFIBRATE	C				UNKNOWN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR	FENOFIBRATE	C				UNKNOWN
ACTIVITIES OF DAILY LIVING IMPAIRED						
ANXIETY						
APHASIA						
ASBESTOSIS						
ATTENTION DEFICIT/HYPERACTIVITY DISORDER						
BLOOD CHOLESTEROL INCREASED						
BLOOD TRIGLYCERIDES INCREASED						
CONDITION AGGRAVATED						
CONSTIPATION						
CONVULSION						
Decreased appetite						
DEPRESSION						
DRUG WITHDRAWAL SYNDROME						
EMOTIONAL DISTRESS						
HEADACHE						
HYPERTENSION						
HYPOTHYROIDISM						
LETHARGY						
MUSCLE SPASMS						
MUSCLE TWITCHING						
PANCREATITIS						
RENAL FAILURE						
RESTLESS LEGS SYNDROME						
SLEEP APNOEA SYNDROME						
TACHYCARDIA						
Terminal insomnia						
URINARY INCONTINENCE						
VOMITING						
WEIGHT DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2009	6900118	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20090106590		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Toxicity to various agents	FENTANYL	S	TRANSDERMAL			
	AMITRIPTYLINE	S	UNKNOWN			
	AMITRIPTYLINE	S	UNKNOWN			
	BUPROPION	S	UNKNOWN			
	TRAMADOL HYDROCHLORIDE	S	UNKNOWN			
	TOPIRAMATE	S	UNKNOWN			
	MORPHINE	S	UNKNOWN			
	CITALOPRAM	S	UNKNOWN			
	CLONAZEPAM	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	HYDROCODONE	S	UNKNOWN			
	UNSPECIFIED INGREDIENT	S	UNKNOWN			
	ATROPINE	C	UNKNOWN			
	NICOTINE	C	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2009	6909095	DIRECT	Y	OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTOLERANCE	EFFEXOR	S				
NERVOUSNESS	LEXAPRO	S				
ANXIETY	CELEXA	C				
NAUSEA	WELLBUTRIN SR	C				
DIARRHOEA						
HYPERHIDROSIS						
RASH						
VOMITING						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Feb-2009	6687881	EXPEDITED (15-DAY)	N	OT	US-TYCO HEALTHCARE/ MALLINCKRODT-T200801054		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	RESTORIL	S		UNK, qd		TYCO
SUICIDAL IDEATION	RESTORIL	S				TYCO
CONVULSION	SEROQUEL	S		UNK, qd		
ASBESTOSIS	SEROQUEL	S				
RENAL FAILURE	WELLBUTRIN	S		UNK, qd		
PANCREATITIS	WELLBUTRIN	S				
THYROID DISORDER	LEXAPRO	S		UNK, qd		
TARDIVE DYSKINESIA	LEXAPRO	S				
WITHDRAWAL SYNDROME	CYMBALTA	S		UNK, qd		
BLOOD PRESSURE INCREASED	CYMBALTA	S				
FEELING ABNORMAL	ZOLOFT	S		UNK		
BLOOD CHOLESTEROL ABNORMAL	ZOLOFT	S				
ROAD TRAFFIC ACCIDENT	XANAX	S		UNK, qd		
STRESS	XANAX	S				
PAIN	XANAX	S				
SLEEP APNOEA SYNDROME	NEURONTIN	S		UNK		
BLOOD TRIGLYCERIDES ABNORMAL	NEURONTIN	S				
WEIGHT DECREASED	TRAZODONE HYDROCHLORIDE	S		UNK		
PALLOR	TRAZODONE HYDROCHLORIDE	S				
MENTAL IMPAIRMENT	EFFEXOR	S		UNK		
MENTAL DISORDER	LISINOPRIL	C				
PANIC ATTACK	FENOFIBRATE	C				
TACHYCARDIA	FENOFIBRATE	C				
APHASIA	LEVOTHYROXINE	C				
HYPOTHYROIDISM	AMBIEN	C				
ANGER	HYDROCHLOROTHIAZIDE	C				

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSKINESIA	HYDROCODONE BITARTRATE	C				
MUSCLE TWITCHING	CARISOPRODOL	C				
ABNORMAL BEHAVIOUR						
AMNESIA						
ANXIETY						
ATTENTION DEFICIT/HYPERACTIVITY DISORDER						
BRUXISM						
CONFUSIONAL STATE						
CONSTIPATION						
DEPRESSION						
DRUG WITHDRAWAL HEADACHE						
EMOTIONAL DISTRESS						
GAIT DISTURBANCE						
HALLUCINATION						
HOSTILITY						
HYPERHIDROSIS						
LETHARGY						
MUSCLE SPASMS						
NIGHTMARE						
NIGHT SWEATS						
PARANOIA						
PYREXIA						
RESTLESS LEGS SYNDROME						
SCREAMING						
Terminal insomnia						
TREMOR						
URINARY INCONTINENCE						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2009	6877968	EXPEDITED (15-DAY)	Y	HO	US-RANBAXY-2009RR-20314	17 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NEPHRITIS ALLERGIC	IBUPROFEN	S				RANBAXY
RENAL FAILURE	LEXAPRO	S		10 mg, UNK	183 DAY	
	LEXAPRO	S		20 mg, UNK		
	ALPRAZOLAM	C		0.5 mg, prn		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2009	6885066	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-14466262	33 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CEREBROVASCULAR ACCIDENT	ABILIFY	S		Started with aripiprazole 10mg		
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2009	6906024	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009164309	26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	HUMIRA	S		1 IN 2 WK		
TREMOR	VICODIN	S	ORAL	5/500, 3 IN 1 D, AS REQUIRED		
ASTHENIA	TETANUS ANTITOXIN	S	INTRAMUSCULAR	ONCE		
DRUG INTERACTION	CELEBREX	S	ORAL	200 mg, 1x/day		PFIZER
WITHDRAWAL SYNDROME	LYRICA	S	ORAL	50 mg, 2x/day		PFIZER
FEELING ABNORMAL	CLINDAMYCIN PHOSPHATE	S	ORAL	100 mg, 3x/day		PFIZER
CONFUSIONAL STATE	LEXAPRO	S	ORAL	20 mg, 1x/day		
DIZZINESS	CHLORMEZANONE	S				
PAIN IN EXTREMITY	AMITRIPTYLINE	S	ORAL	75 mg, 1x/day at night		
LOCALISED INFECTION	RIZATRIPTAN BENZOATE	S	ORAL	10 mg, 1x/day		
LIMB INJURY	CYCLOBENZAPRINE HYDROCHLORIDE	S	ORAL	10 mg, every 8 hours as required		
	BUPROPION	S	ORAL	150 mg, 1x/day		
	MINOCYCLINE HYDROCHLORIDE	S	ORAL	100 mg, 2x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2009	6914469	DIRECT	N	HO,LT,RI		86 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABDOMINAL PAIN UPPER	LEXAPRO	S		1/2 TABLET EVERY DAY	2 WEEK	
HAEMATEMESIS						
SCREAMING						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Feb-2009	6691999	EXPEDITED (15-DAY)	N	OT	A0736099A	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING ABNORMAL	WELLBUTRIN	S	ORAL		4 YR	GLAXOSMITHKLINE
CONFUSIONAL STATE	XANAX	S	UNKNOWN		4 YR	
ROAD TRAFFIC ACCIDENT	SEROQUEL	S	UNKNOWN		4 YR	
DYSKINESIA	LEXAPRO	S	UNKNOWN		3 YR	
BRUXISM	RESTORIL	S	UNKNOWN		4 YR	
TARDIVE DYSKINESIA	CYMBALTA	S	UNKNOWN		4 YR	
HALLUCINATION	ZOLOFT	S				
HYPERHIDROSIS	NEURONTIN	S				GLAXOSMITHKLINE
HEADACHE	TRAZODONE HYDROCHLORIDE	S				
PERFORMANCE STATUS DECREASED	EFFEXOR	S				
CONVULSION	LISINOPRIL	C				
SLEEP DISORDER	FENOFIBRATE	C				
NIGHTMARE	LEVOTHYROXINE	C				GLAXOSMITHKLINE
SUICIDAL IDEATION	AMBIEN	C				
SUICIDE ATTEMPT	HYDROCHLOROTHIAZIDE	C				
INTENTIONAL OVERDOSE	HYDROCODONE BITARTRATE & ACETAMINOPHEN	C				
WEIGHT DECREASED	CARISOPRODOL	C				
ACTIVITIES OF DAILY LIVING IMPAIRED						
ANGER						
ANXIETY						
APHASIA						
ASBESTOSIS						
ATTENTION DEFICIT/HYPERACTIVITY DISORDER						
BACK PAIN						
BLOOD CHOLESTEROL ABNORMAL						
BLOOD PRESSURE INCREASED						
BLOOD TRIGLYCERIDES ABNORMAL						
COMMUNICATION DISORDER						
CONSTIPATION						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Decreased appetite						
DEPRESSION						
DRUG DEPENDENCE						
EMOTIONAL DISTRESS						
HEAD INJURY						
HYPERTENSION						
HYPOTHYROIDISM						
INSOMNIA						
LETHARGY						
MEMORY IMPAIRMENT						
MENTAL DISORDER						
MUSCLE TWITCHING						
NIGHT SWEATS						
OVERDOSE						
PAIN						
PALLOR						
PANCREATITIS						
PANIC REACTION						
PARANOIA						
PYREXIA						
REGURGITATION						
RENAL FAILURE						
RESTLESS LEGS SYNDROME						
SEDATION						
SLEEP APNOEA SYNDROME						
STRESS						
TACHYCARDIA						
Terminal insomnia						
THYROID DISORDER						
TREMOR						
URINARY INCONTINENCE						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VOMITING						
WITHDRAWAL SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Feb-2009	6916343	EXPEDITED (15-DAY)	Y	CA	1000003842	< 1 DAY	Male	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal drugs affecting foetus	LEXAPRO	S	TRANSPLACENTAL	10 MG (10 MG,1 IN 1 D),TRANSPLACENTAL		
HYPOSPADIAS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2009	6915720	DIRECT	Y			85 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	LEXAPRO	S	ORAL	10 MG DAILY PO		
DRUG INTOLERANCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2009	6917008	DIRECT	Y	HO		61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	ZYVOX	S	ORAL	600MG BID PO	14 DAY	PFIZER
DRUG INTERACTION	LEXAPRO	S	ORAL	20MG DAILY PO	7 MTH	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2009	6909487	EXPEDITED (15-DAY)	Y	DE	1000003701	76 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
STRESS	REQUIP	C				
	SINEMET	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2009	6921030	EXPEDITED (15-DAY)	N	DE	1000003916	56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S				
ASPHYXIA						
DEATH OF RELATIVE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2009	6921514	DIRECT	N	OT		71 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	ONE TABLET BY MOUTH PER DAY PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2009	6911475	EXPEDITED (15-DAY)	Y	DE	PHHY2009US05428	66 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINA BIFIDA	CLOZARIL	S	ORAL	300 mg/day		NOVARTIS
	VALIUM	S	ORAL	6.5 mg daily		
	LEXAPRO	S	ORAL	10 mg daily		
	MS CONTIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2009	6913352	EXPEDITED (15-DAY)	N	HO,OT	US-ROCHE-613546	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLADDER NEOPLASM	PEGINTERFERON ALFA-2A	S	UNKNOWN	FORM: PRE-FILLED SYRINGE		ROCHE
HYPERSENSITIVITY	RIBAVIRIN	S	UNKNOWN			ROCHE
ANAEMIA	MECLIZINE	S	UNKNOWN			
DYSTONIA	TRAMADOL HYDROCHLORIDE	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	TRAZODONE HYDROCHLORIDE	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2009	6926310	EXPEDITED (15-DAY)	Y	OT	1000003934		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S		5 MG; 10 MG;		
ANXIETY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2009	6926328	EXPEDITED (15-DAY)	Y	HO,OT	1000003961		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
POST PROCEDURAL HAEMORRHAGE	LEXAPRO	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2009	6929299	EXPEDITED (15-DAY)	Y	HO,OT	1000003303	81 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
NAUSEA	ARICEPT	C				
Coordination abnormal	CELEBREX	C				
CATARACT	ASPIRIN	C				
	GLUCOSAMINE(TABLETS)	C				
	NAMENDA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2009	6871738	EXPEDITED (15-DAY)	Y	DE	1000003184	76 YR	Male	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL		
	TEMAZEPAM	C				
	OXAZEPAM	C				
	DORMICUM (TABLETS)	C				
	NEXIUM (TABLETS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2009	6871748	EXPEDITED (15-DAY)	Y	DE	1000003187	47 YR	Male	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	TEMAZEPAM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2009	6916531	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20090204798	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
IRRITABLE BOWEL SYNDROME	RISPERDAL	S	ORAL			
BLOOD GLUCOSE INCREASED	LEXAPRO	S	ORAL			
BLOOD GLUCOSE DECREASED	STRATTERA	S	ORAL			
ASTHENIA						
DYSPEPSIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2009	6917199	EXPEDITED (15-DAY)	Y	OT	PHEH2009US01757	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RENAL IMPAIRMENT	FEMARA	S	ORAL	2.5 mg, QD		NOVARTIS
LABORATORY TEST ABNORMAL	SYNTHROID	S		UNK	3650 DAY	
CONSTIPATION	LIPITOR	S		UNK	1825 DAY	
	LEXAPRO	S		UNK	244 DAY	
	CALCIUM	S		UNK	730 DAY	
	NEURONTIN	S		UNK		
	UNSPECIFIED INGREDIENT	S		UNK		
	UNSPECIFIED INGREDIENT	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2009	6918131	NON-EXPEDITED			US-ABBOTT-08P-163-0494375-00		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	SIMCOR	S		500mg/20mg		
TENSION	LEXAPRO	S				
MUSCLE TWITCHING	XANAX	C				
MUSCLE SPASMS	ALLEGRA	C				
FLUSHING	UNSPECIFIED INGREDIENT	C				
NIGHT SWEATS	ASA	C		At times		
DIZZINESS						
PARAESTHESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2009	6918355	NON-EXPEDITED			US-ABBOTT-09P-163-0496261-00		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FLUSHING	SIMCOR	S				
	LEXAPRO	S				
	METFORMIN	C				
	LEXAPRO	C				
	ASA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2009	6681144	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2008051192		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	XANAX	S				PFIZER
TARDIVE DYSKINESIA	XANAX	S				PFIZER
RENAL FAILURE	XANAX	S				PFIZER

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION	ZOLOFT	S				PFIZER
CONVULSION	ZOLOFT	S				PFIZER
DEPRESSION	NEURONTIN	S				PFIZER
PARANOIA	NEURONTIN	S				PFIZER
HYPERTENSION	TRAZODONE HYDROCHLORIDE	S				
PANCREATITIS	SEROQUEL	S				
ASBESTOSIS	WELLBUTRIN	S				
BLOOD CHOLESTEROL INCREASED	LEXAPRO	S				
BLOOD TRIGLYCERIDES ABNORMAL	RESTORIL	S				
WITHDRAWAL SYNDROME	CYMBALTA	S		UNK		
PANIC ATTACK	EFFEXOR	S		UNK		
TACHYCARDIA	LISINOPRIL	C				
HYPOTHYROIDISM	FENOFIBRATE	C				
ROAD TRAFFIC ACCIDENT	FENOFIBRATE	C				
HYPERHIDROSIS	LEVOTHYROXINE	C				
PAIN	AMBIEN	C				
SLEEP APNOEA SYNDROME	HYDROCHLOROTHIAZIDE	C				
AMNESIA	HYDROCODONE BITARTRATE & ACETAMINOPHEN	C				
URINARY INCONTINENCE	CARISOPRODOL	C				
ANGER						
BRUXISM						
FEELING ABNORMAL						
INCORRECT DOSE ADMINISTERED						
INSOMNIA						
PYREXIA						
TREATMENT NONCOMPLIANCE						
VOMITING						
WEIGHT DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2009	6915666	EXPEDITED (15-DAY)	Y	HO,LT	AU-AMGEN-US333842	46 YR	Male	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
THROMBOCYTOPENIA	ENBREL	S	SUBCUTANEOUS	25mg 2 vials once a week		
DRUG INTERACTION	VALPROATE SODIUM	C	UNKNOWN			
MOUTH ULCERATION	LITHIUM	C	UNKNOWN	unknown		
HEADACHE	LEXAPRO	S	UNKNOWN	20mg		
RESPIRATORY TRACT INFECTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2009	6922149	NON-EXPEDITED	N		A0722886A	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	LAMICTAL	S	ORAL	25MG Per day		GLAXOSMITHKLINE
EMOTIONAL DISORDER	PAXIL	S	ORAL	10MG Per day	1 YR	GLAXOSMITHKLINE
STRESS	LUNESTA	S	ORAL	3MG At night	2 DAY	GLAXOSMITHKLINE
RASH PRURITIC	AMBIEN	S	ORAL	10MG At night		
TENSION	LEXAPRO	S				
NERVOUSNESS	UNSPECIFIED INGREDIENT	C				GLAXOSMITHKLINE
SOMNOLENCE	VITAMINS	C				
DIPLOPIA						
DRUG HYPERSENSITIVITY						
DRY MOUTH						
DYSGEUSIA						
RHINORRHOEA						
TINNITUS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2009	6922230	NON-EXPEDITED	N		A0725838A	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG SCREEN POSITIVE	LAMICTAL	S	ORAL			GLAXOSMITHKLINE
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2009	6922405	NON-EXPEDITED	N		A0732290A	21 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LAMICTAL	S	ORAL	50MG Per day		GLAXOSMITHKLINE
FATIGUE	LEXAPRO	S	ORAL	20MG Per day		
	UNSPECIFIED INGREDIENT	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2009	6922457	NON-EXPEDITED	N		A0733893A	28 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	LAMICTAL	S	ORAL	300MG Per day	6 MTH	GLAXOSMITHKLINE
	LEXAPRO	S				
	STRATTERA	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2009	6923658	NON-EXPEDITED	N		A0714332A	67 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	IMITREX	S	SUBCUTANEOUS	6MG As required		GLAXOSMITHKLINE
DRUG INTERACTION	LEXAPRO	S	ORAL	10MG Per day	2 DAY	
	SUMATRIPTAN SUCCINATE	C				GLAXOSMITHKLINE
	VITAMIN	C				
	CALCIUM	C				
	PRILOSEC	C				GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2009	6539207	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2008007185	46 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL BEHAVIOUR	CHANTIX	S		UNK	19 DAY	PFIZER
SUICIDAL IDEATION	ALTACE	C				
ACTIVITIES OF DAILY LIVING IMPAIRED	TRIAMTERENE AND HYDROCHLOROTHIAZIDE	C				
NAUSEA	ACETYLSALICYLIC ACID	C				
ABNORMAL DREAMS	LEXAPRO	S		10 mg, 1x/day		
MALAISE	LEXAPRO	S				
AGITATION						
DRUG INEFFECTIVE						
DRUG INTERACTION						
MENTAL DISORDER						
PERSONALITY CHANGE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2009	6890070	EXPEDITED (15-DAY)	Y	DE	1000003496	34 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	10 MG (10 MG, 1IN 1 D), ORAL		
MOOD ALTERED	AMBIEN	C				
GUN SHOT WOUND	LUNESTA	C				
DRUG SCREEN POSITIVE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2009	6932061	EXPEDITED (15-DAY)	Y	DE	GXKR2009US01983	25 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TOXICITY TO VARIOUS AGENTS	DEXTROMETHORPHAN	S				
LOSS OF CONSCIOUSNESS	TEMAZEPAM	S				
FALL	ZYPREXA	S				
UNRESPONSIVE TO STIMULI	LEXAPRO	S				
PULMONARY CONGESTION	AMBIEN	S				
BRONCHOPNEUMONIA	ALCOHOL	S		EXCESSIVE AMOUNT, UNKNOWN		
	NAPROXEN (NAPROXEN)	C				
	RISPERDAL	C				
	LITHIUM (LITHIUM)	C				
	METOCARBAMOL (METOCARBAMOL)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2009	6941423	DIRECT	N	OT		33 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CHEST PAIN	LEXAPRO	S				FOREST
CHILLS						
CONVERSION DISORDER						
DRUG DEPENDENCE						
GENERAL PHYSICAL HEALTH DETERIORATION						
INCORRECT DRUG ADMINISTRATION DURATION						
MUSCLE TWITCHING						
NAUSEA						
PALPITATIONS						
PARAESTHESIA						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2009	6942341	DIRECT	N			16 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	LEXAPRO	S	ORAL	20MG 1 A DAY PO		
FEELING ABNORMAL						
NERVOUSNESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2009	6929432	EXPEDITED (15-DAY)	Y	CA,OT	US-BRISTOL-MYERS SQUIBB COMPANY-14530828		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CLEFT PALATE	ABILIFY	S	TRANSPLACENTAL			
	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2009	6943456	EXPEDITED (15-DAY)	N	HO	1000004996	78 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
FACIAL BONES FRACTURE	NORVASC	C				
FALL	DIOVAN (TABLETS)	C				
THYROID NEOPLASM	FOSAMAX	C				
HEADACHE	ADVAIR (AEROSOL FOR INHALATION)	C				
FATIGUE	COMBIVENT (AEROSOL FOR INHALATION)	C				
	CALCIUM (TABLETS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Mar-2009	6908800	EXPEDITED (15-DAY)	Y	OT	US-JNJFOC-20090202630	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEAFNESS BILATERAL	RISPERDAL	S	ORAL			
	LEXAPRO	S	ORAL			
	WELLBUTRIN XL	S	ORAL	450 (units unspecified) qd		
	SYNTHROID	C	ORAL			
	LITHIUM CARBONATE	C	UNKNOWN	600 (units unspecified) bid		
	PROVIGIL	C	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2009	6947224	DIRECT	N	DE,OT		55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	SEROQUEL	S		UNKNOWN		
	LEXAPRO	S		UNKNOWN		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2009	6954283	EXPEDITED (15-DAY)	N	OT	1000005097	62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
SCREAMING	DILANTIN	C				
	LANTUS	C				
	SYNTHROID	C				
	ACTOS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Mar-2009	6948526	DIRECT				49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
URTICARIA	PROZAC	S		4-1-08 - 5-7-08		
EPISTAXIS	LEXAPRO	S		3-12-08 - 4-2-08		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Mar-2009	6950510	EXPEDITED (15-DAY)	Y	HO	1000005068	80 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DIARRHOEA	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
WEIGHT DECREASED	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL; 20 MG (20 MG, 1 IN 1 D), ORAL		
FALL	ASPIRIN	C				
ANAEMIA MEGALOBLASTIC	METFORMIN (TABLETS)	C				
	HYDROCHLOROTHIAZIDE	C				
	LIPITOR	C				
	LISINOPRIL	C				
	DETROL	C				
	ATENOLOL	C				
	FOSAMAX	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Mar-2009	6957976	EXPEDITED (15-DAY)	Y	DE	1000005241		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Mar-2009	6541632	EXPEDITED (15-DAY)	Y	HO	US-PFIZER INC-2008005876	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOTENSION	DETROL LA	S	ORAL	4 mg, 1x/day	828 DAY	PFIZER
SINUS TACHYCARDIA	LEXAPRO	S	ORAL	10 mg, 1x/day	18 DAY	
ELECTROCARDIOGRAM T WAVE INVERSION	REBOXETINE	S	ORAL	1 mg, 1x/day		PFIZER
	THIAMINE HYDROCHLORIDE	C	ORAL			
	FOLIC ACID	C	ORAL	QD		
	MULTIVITAMINS	C	ORAL	1,QD		
	LISINOPRIL	C	ORAL	1,QD		
	VERAPAMIL HYDROCHLORIDE	C	ORAL	1,QD		
	K-DUR	C	ORAL			
	MAGNESIUM OXIDE	C	ORAL	2 TABS,BID		
	SYNTHROID	C	ORAL	QD		
	AMITIZA	C	ORAL	BID		
	CYANOCOBALAMIN	C	INTRAMUSCULAR	QMO		
	METOPROLOL TARTRATE	C	ORAL	1,BID		
	ASA	C	ORAL	QD		
	CELEBREX	C		1,QD		
	PROTONIX	C		1,QD		
	PREMARIN	C		1,QD		
	TRAMADOL HYDROCHLORIDE	C		1,Q 6 HOURS PRN		
	TRAZODONE HYDROCHLORIDE	C		1,QHS		
	AMITRIPTYLINE	C		1,QPM		
	POTASSIUM CHLORIDE	C		1,QD		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Mar-2009	6941011	EXPEDITED (15-DAY)	Y	OT	1000004984	39 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERHIDROSIS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
MUSCLE TWITCHING	PROTIUM (TABLETS)	C				
VOMITING	LARIG (TABLETS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Mar-2009	6955013	DIRECT	Y				Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MEDICATION ERROR	NAMENDA	S				
CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Mar-2009	6955120	EXPEDITED (15-DAY)	Y	OT	DSA_33316_2009	47 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSPHAGIA	XENAZINE	S	ORAL	6.25 MG QD ORAL		
DYSPNOEA	LEXAPRO	S		DF		
FALL	INVEGA	C				
INSOMNIA	DEPAKOTE	C				
ANXIETY	DEPLIN	C				
DISORIENTATION	NAMENDA	C				
DRUG INTERACTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Mar-2009	6948669	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20090303572		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSTONIA	TRAMADOL HYDROCHLORIDE	S	UNKNOWN			
BLADDER NEOPLASM	RIBAVIRIN	S	UNKNOWN			
ANAEMIA	PEGASYS	S				
PHARYNGEAL OEDEMA	MECLIZINE	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	TRAZODONE HYDROCHLORIDE	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Mar-2009	6902811	EXPEDITED (15-DAY)	Y	HO,OT	1000003606	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BIOTIN DEFICIENCY	LEXAPRO	S	TRANSPLACENTAL	10 MG (10 MG, 1 IN 1 D), TRANSPLACENTAL		
CONVULSION NEONATAL	KLONOPIN	C				
SEPSIS NEONATAL	LORTAB	C				
NEONATAL RESPIRATORY DEPRESSION	HEPATITIS B VACCINE (INJECTION)	C				
ANAEMIA NEONATAL						
AORTIC VALVE DISEASE						
Apnoea neonatal						
BLOOD PRESSURE DECREASED						
HEART RATE INCREASED						
Maternal drugs affecting foetus						
MECONIUM IN AMNIOTIC FLUID						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Mar-2009	6949654	EXPEDITED (15-DAY)	N	HO,OT	US-PFIZER INC-2009182620		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERSENSITIVITY	MECLIZINE HYDROCHLORIDE	S				PFIZER
BLADDER NEOPLASM	TRAZODONE HYDROCHLORIDE	S				
	TRAMADOL HYDROCHLORIDE	S				
	INTERFERON ALFA NOS	S		180 ug, weekly	13 DAY	
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Mar-2009	6950210	EXPEDITED (15-DAY)		OT	PHEH2009US02691	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EXTRASYSTOLES	LOPRESSOR	S	ORAL	25 mg, QID		NOVARTIS
BLOOD PRESSURE INCREASED	LEXAPRO	S	ORAL	5 mg, QD		
ABDOMINAL PAIN UPPER	VALIUM	C				
DECREASED APPETITE	KLONOPIN	C				
DRUG INTERACTION	ATIVAN	C				
	SYNTHROID	C				
	EFFEXOR	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Mar-2009	6957202	EXPEDITED (15-DAY)	N	OT	1000005376	40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PELVIC CONGESTION	LEXAPRO	S	ORAL	SEE IMAGE		
THROMBOSIS						
UTERINE CYST						
VAGINAL HAEMORRHAGE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Mar-2009	6958946	DIRECT	N	CA,OT		22 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal drugs affecting foetus	LEXAPRO	S	ORAL	1 A DAY PO 6-9 MONTHS		
ATRIAL SEPTAL DEFECT						
LUNG DISORDER						
NEONATAL DISORDER						
PREMATURE BABY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Mar-2009	6951594	EXPEDITED (15-DAY)	Y	HO	US-ROCHE-621957	51 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERTENSION	KLONOPIN	S	ORAL			ROCHE
DYSARTHRIA	INDERAL	C				
Intentional drug misuse	ALLEGRA-D	C				
DRUG INTERACTION	LOTENSIN	C		DRUG REPORTED: LOTENSION		
	RITALIN	S	UNKNOWN			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Mar-2009	6959381	DIRECT	N	LT		16 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10MG ONCE A DAY PO		
CONDITION AGGRAVATED						
DEPRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Apr-2009	6969788	DIRECT	N	OT		26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ASTHENIA	LEXAPRO	S	ORAL	5MG/5ML 1 PER DAY PO		
DISTURBANCE IN ATTENTION						
EDUCATIONAL PROBLEM						
EXERCISE TOLERANCE DECREASED						
THERAPY CESSATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Apr-2009	6958779	EXPEDITED (15-DAY)	Y	DE	US-ABBOTT-09P-163-0564051-00		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Apr-2009	6958841	EXPEDITED (15-DAY)	N	HO,OT	US-WATSON-2009-01994	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERSENSITIVITY	TRAZODONE HYDROCHLORIDE	S	UNKNOWN	UNK		WATSON
DYSKINESIA	MECLIZINE HYDROCHLORIDE	S	UNKNOWN	UNK		WATSON
PHARYNGEAL OEDEMA	TRAMADOL HYDROCHLORIDE	S	UNKNOWN	UNK		WATSON
BLADDER NEOPLASM	PEGINTERFERON ALFA-2A	S	UNKNOWN	180 ug, 1/week	13 DAY	
BLOOD URINE PRESENT	RIBAVIRIN	S	UNKNOWN	1000 mg, daily	13 DAY	
ANAEMIA	LEXAPRO	S	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Apr-2009	6966743	EXPEDITED (15-DAY)	Y	OT	1000005572	25 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Apr-2009	6970602	EXPEDITED (15-DAY)	Y	HO	1000005553	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CEREBROVASCULAR ACCIDENT	LEXAPRO	S	ORAL	30 MG (30 MG, 1 IN 1 D), ORAL; 8-9 TABLETS		
ACCIDENTAL OVERDOSE	AMBIEN	C				
OVERDOSE	XANAX	C				
	LAMICTAL	C				
	NEURONTIN	C				
	PAIN PATCH (NOS)	C				
	LISINOPRIL	C				
	AMITRIPTYLINE	C				
	OXYCONTIN	C				
	OXYGEN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Apr-2009	6970637	EXPEDITED (15-DAY)	Y	OT	1000005573	25 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Apr-2009	6987802	EXPEDITED (15-DAY)	Y	OT	1000005468	25 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S				
	LAMICTAL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2009	6958657	EXPEDITED (15-DAY)	Y	DE	1000005307	32 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TOXICITY TO VARIOUS AGENTS	LEXAPRO	S				
COMPLETED SUICIDE	ZYPREXA	S		10 MG (10 MG, 1 IN 1 D)		
DILATATION VENTRICULAR	SEROQUEL	S				
	TRAZODONE	S				
	BENADRYL	S				
	DILANTIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2009	6958677	EXPEDITED (15-DAY)	Y	DE	1000005305	78 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TOXICITY TO VARIOUS AGENTS	LEXAPRO	S				
COMPLETED SUICIDE	MIRTAZAPINE	S				
PNEUMONIA	SERTRALINE HYDROCHLORIDE	S				
	AMITRIPTYLINE	S				
	ZOLPIDEM	S				
	LORAZEPAM	S				
	TRAZODONE	S				
	PHENYTOIN	S				
	ACICLOVIR	S				
	ZYPREXA	S		2.5 MG (2.5 MG,1 IN 1 D)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2009	6958683	EXPEDITED (15-DAY)	Y	DE	1000005306	27 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TOXICITY TO VARIOUS AGENTS	LEXAPRO	S				
ACCIDENTAL DEATH	ZYPREXA	S				
DRUG LEVEL INCREASED	FLUOXETINE	S				
SKIN INJURY	KEMADRIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2009	6959757	EXPEDITED (15-DAY)	Y	HO	US-ASTRAZENECA-2009UW07689	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MENTAL STATUS CHANGES	ZESTORETIC	S	ORAL	20/12.5 MG		
DYSARTHRIA	DESVENLAFAXINE SUCCINATE	S	ORAL		107 DAY	
CONDITION AGGRAVATED	IBUPROFEN	S				
HYPOKALAEMIA	LYRICA	S				
POLYMEDICATION	LEXAPRO	S				
HYPERTENSION	CLONAZEPAM	S				
ASTHENIA	ABILIFY	S	UNKNOWN			
HEADACHE	FLUTICASONE	S		2 SPRAYS DAILY		
	LORATADINE	S				
	VICODIN	S		5/500		
	AMBIEN	S	ORAL			
	VIVELLE	S		0.1 MG		
	ROBAXIN	S				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2009	6961889	EXPEDITED (15-DAY)	Y	DE	1000005304	25 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TOXICITY TO VARIOUS AGENTS	LEXAPRO	S				
FALL	ZYPREXA	S		(10 MG)		
LOSS OF CONSCIOUSNESS	LITHIUM	S				
BRONCHOPNEUMONIA	RISPERDAL	S				
PULMONARY CONGESTION	AMBIEN	S				
CONTUSION	TEMAZEPAM	S				
	NAPROXEN	S				
	METHOCARBAMOL	S				
	ALCOHOL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2009	6961937	EXPEDITED (15-DAY)	Y	DE	1000005308	42 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TOXICITY TO VARIOUS AGENTS	LEXAPRO	S				
ALCOHOL USE	ZYPREXA	S		20 MG (20 MG, 1 IN 1 D)		
SNORING	LUNESTA	S				
PULMONARY OEDEMA	SEROQUEL	S				
HEPATIC STEATOSIS	VISTARIL	S				
ARTERIOSCLEROSIS	DEPAKOTE	S				
ACCIDENTAL DEATH						
ANTIPSYCHOTIC DRUG LEVEL ABOVE THERAPEUTIC						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Apr-2009	6898476	EXPEDITED (15-DAY)	Y	DS,OT	1000003546	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEVELOPMENTAL DELAY	LEXAPRO	S	TRANSPLACENTAL	5 MG (5 MG,1 IN 1 D),TRANSPLACENTAL		
ABASIA						
Developmental hip dysplasia						
FAILURE TO THRIVE						
FEEDING DISORDER NEONATAL						
HYPOSPADIAS						
HYPOTONIA						
Maternal drugs affecting foetus						
UMBILICAL CORD AROUND NECK						
WEIGHT GAIN POOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Apr-2009	6966738	EXPEDITED (15-DAY)	Y	DE,HO	1000005560	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	5 MG (5 MG,1 IN 1 D),ORAL ; 10 MG (10 MG,1 IN 1 D),ORAL ; 20 MG (20 MG,1 IN 1 D),ORAL		
	CYMBALTA	S	ORAL	ORAL		
	ATIVAN	C				
	ABILIFY	C				
	REMERON	C				
	WELLBUTRIN	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Apr-2009	6970922	EXPEDITED (15-DAY)	Y	HO	1000005611	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSARTHRIA	LEXAPRO	S		20 MG (20 MG,1 IN 1 D)		
MENTAL STATUS CHANGES	UNSPECIFIED INGREDIENT	S	ORAL	(DAILY),ORAL		
HYPOKALAEMIA	IBUPROFEN	S		2400 MG (800 MG,3 IN 1 D)		
HYPERTENSION	LYRICA	S		75 MG (75 MG,1 IN 1 D)		
HEADACHE	CLONAZEPAM	S		2 MG (1 MG,2 IN 1 D)		
ASTHENIA	ABILIFY	S		30 MG (15 MG,2 IN 1 D)		
CONFUSIONAL STATE	FLUTICASONE	S		(2 SPRAYS DAILY)		
ELECTROCARDIOGRAM ST SEGMENT ABNORMAL	LORATADINE	S		10 MG (10 MG,1 IN 1 D)		
BLOOD POTASSIUM DECREASED	VICODIN	S		(PRN)		
WHITE BLOOD CELL COUNT INCREASED	ZESTORETIC	S		(DAILY)		
HAEMATOCRIT INCREASED	AMBIEN	S		10 MG (10 MG,1 IN 1 D)		
MASTOID DISORDER	VIVELLE	S	TRANSDERMAL	(0.1 MG),TRANSDERMAL		
	ROBAXIN	S		2250 MG (750 MG,3 IN 1 D)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Apr-2009	6959512	EXPEDITED (15-DAY)	Y	HO	235567K07USA	43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	REBIF	S	SUBCUTANEOUS	44 MCG, 3 IN 1 WEEKS, SUBCUTANEOUS		
INJECTION SITE ERYTHEMA	LEXAPRO	S		40 MG, 20 MG		
INJECTION SITE PAIN	IBUPROFEN (IBUPROFEN)	C				
DEPRESSED MOOD	SYNTHROID	C				
GAIT DISTURBANCE	OCYBUTIN (OXYBUTYNIN/ 00538901/)	C				
FALL						
SELF-INJURIOUS IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Apr-2009	6965479	EXPEDITED (15-DAY)	N	DS,OT	PHEH2009US03323		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOTHALAMO-PITUITARY DISORDER	TRILEPTAL	S				NOVARTIS
DISORIENTATION	LEXAPRO	S				
HEADACHE						
HYPERACUSIS						
HYPERSENSITIVITY						
MUSCLE SPASMS						
SENSORY LOSS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Apr-2009	6966681	NON-EXPEDITED	N		US-ASTRAZENECA-2009UW01598	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
JOINT SWELLING	ATENOLOL	S	ORAL			
BLOOD PRESSURE INCREASED	XYREM	S	ORAL			
DYSPEPSIA	RAMIPRIL	S	UNKNOWN			
ABDOMINAL PAIN	LEXAPRO	S	UNKNOWN			
ABDOMINAL DISTENSION	CYMBALTA	S	UNKNOWN			
	SIMVASTATIN	S	UNKNOWN			
	LYRICA	S	UNKNOWN			
	TRIAMTERENE AND HYDROCHLOROTHIAZIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Apr-2009	6976703	EXPEDITED (15-DAY)	Y	OT	1000005675	60 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DISTURBANCE IN ATTENTION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
SOMNOLENCE	ANXICALM (TABLETS)	C				
	LIPITOR	C				
	ZOTON (CAPSULES)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Apr-2009	6969645	EXPEDITED (15-DAY)	Y	DE,HO	US-ASTRAZENECA-2009UW09280		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DISEASE PROGRESSION	NEXIUM	S	ORAL			
	CELEBREX	S				
	COLACE	S				
	LEXAPRO	S				
	MEGACE	S				
	OXYCODONE HYDROCHLORIDE	S				
	SYNTHROID	S				
	XANAX	S				
	SELUMETINIB	S	ORAL		44 DAY	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Apr-2009	6970467	EXPEDITED (15-DAY)	N	OT	A0777897A		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AMNESIA	LAMICTAL	S	ORAL		6 YR	GLAXOSMITHKLINE
SOMNOLENCE	PAXIL	S	ORAL			GLAXOSMITHKLINE
HALLUCINATION	KLONOPIN	S				
DEPRESSION	LEXAPRO	S				
	BUPROPION	S			6 YR	TEVA
	HUMULIN R	C				
	SPIRIVA	C				
	PLAVIX	C				
	SIMVASTATIN	C				
	UNSPECIFIED INGREDIENT	C				GLAXOSMITHKLINE
	UNSPECIFIED INGREDIENT	C				
	METOPROLOL TARTRATE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Apr-2009	6970499	EXPEDITED (15-DAY)	Y	HO	US-ABBOTT-09P-163-0566868-00	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSARTHRIA	VICODIN	S	UNKNOWN	5/500 as needed		
CONDITION AGGRAVATED	LEXAPRO	S	UNKNOWN			
HYPOKALAEMIA	IBUPROFEN	S	UNKNOWN			
POLYMEDICATION	DESVENLAFAXINE SUCCINATE	S	ORAL			
MENTAL STATUS CHANGES	DESVENLAFAXINE SUCCINATE	S				
HYPERTENSION	ABILIFY	S	UNKNOWN			
HEADACHE	AMBIEN	S	ORAL			
ASTHENIA	CLONAZEPAM	S	UNKNOWN			
	FLUTICASONE	S	UNKNOWN	sprays		
	LORATADINE	S	UNKNOWN			
	LYRICA	S	ORAL			
	METHOCARBAMOL	S	UNKNOWN			
	VIVELLE	S	TRANSDERMAL			
	ZESTORETIC	S	UNKNOWN	20/12.5 daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Apr-2009	6985715	EXPEDITED (15-DAY)	N	OT	CHPA2009US09086		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BRADYCARDIA	ACETAMINOPHEN \DIPHENHYDRAMINE HYDROCHLORIDE \PHENYLEPHRINE HYDROCHLORIDE	S	ORAL	6 TSP, ONCE/SINGLE, ORAL		
DYSPNOEA	ACETAMINOPHEN \DEXTROMETHORPHAN \PHENYLEPHRINE	S	ORAL	6 TSP, ONCE/SINGLE, ORAL		
DIZZINESS	LEXAPRO	S		ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Apr-2009	6976336	DIRECT	Y	OT		86 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD SODIUM DECREASED	LEXAPRO	S	ORAL	10MG QD PO		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Apr-2009	6983710	DIRECT	N	OT		43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEADACHE	LEXAPRO	S	ORAL	1 TABLET 1X DAY PO		
APHASIA						
DECREASED APPETITE						
NAUSEA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Apr-2009	6981382	EXPEDITED (15-DAY)	Y	OT	1000005796	84 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FALL	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL, 20 MG (20 MG, 1 IN 1 D), ORAL, 30 MG (30 MG, 1 IN 1 D), ORAL,		
OVERDOSE						
PELVIC FRACTURE						
URINARY RETENTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Apr-2009	6985142	DIRECT	N			44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	LEXAPRO	S	ORAL	10MG 1 TABLET DAILY PO		
ANXIETY						
CONFUSIONAL STATE						
CRYING						
EYE DISORDER						
FEAR						
FORMICATION						
HEART RATE INCREASED						
HYPERACUSIS						
IMPAIRED DRIVING ABILITY						
MENTAL IMPAIRMENT						
PHOTOPHOBIA						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Apr-2009	6985357	DIRECT	N	DE		33 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGGRESSION	LEXAPRO	S	ORAL	ONCE DAILEY PO		
MOOD SWINGS	XANAX	C				
COMPLETED SUICIDE	AMBIEN	C				
GUN SHOT WOUND						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Apr-2009	6962502	EXPEDITED (15-DAY)	N	DE	US-BRISTOL-MYERS SQUIBB COMPANY-14574263	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUDDEN DEATH	ABILIFY	S	ORAL		4 YR	
	LEXAPRO	S	ORAL			
	ATENOLOL	C				
	PREVACID	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Apr-2009	6984168	DIRECT				33 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG DISPENSING ERROR	LEXAPRO	S				
MEDICATION ERROR	LIPITOR	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Apr-2009	6985889	DIRECT	Y			52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	EFFEXOR XR	S	ORAL	37.5 MG DAILY (2X) ORAL		
LETHARGY	LEXAPRO	S	ORAL	10 MG 1 X ORAL		
DECREASED APPETITE						
DEPRESSION						
DYSGEUSIA						
HYPOPHAGIA						
IRRITABILITY						
MENTAL IMPAIRMENT						
POLLAKIURIA						
TONGUE DISCOLOURATION						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Apr-2009	6986609	EXPEDITED (15-DAY)	N	OT	1000001578	32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING ABNORMAL	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL, 20 MG (20 MG, 1 IN 1 D), ORAL, 20 MG (20 MG, 1 IN 1 D), ORAL		
ABDOMINAL DISCOMFORT						
ANXIETY						
DEPRESSED MOOD						
DRUG DOSE OMISSION						
INAPPROPRIATE SCHEDULE OF DRUG ADMINISTRATION						
MUSCULAR WEAKNESS						
OBSESSIVE THOUGHTS						
SELF-INJURIOUS IDEATION						
THERAPY CESSATION						
TREATMENT NONCOMPLIANCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Apr-2009	6910170	EXPEDITED (15-DAY)	Y	HO	1000003722	51 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERTENSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL		
DRUG INTERACTION	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL		
MALAISE	RITALIN	S				
DYSARTHRIA	KLONOPIN	S	ORAL	2 MG (0.5 MG,4 IN 1 D),ORAL		
	INDERAL	C				
	LOTENSION	C				
	ALLEGRA-D	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Apr-2009	6953720	EXPEDITED (15-DAY)	Y	HO	1000005156	48 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Apr-2009	6986715	DIRECT	N	OT		42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
QUALITY OF LIFE DECREASED	LEXAPRO	S	ORAL	NOW: .5MG DAILY PO		
FAMILY STRESS						
IMPAIRED WORK ABILITY						
PARAESTHESIA						
TINNITUS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Apr-2009	6436152	EXPEDITED (15-DAY)	Y	DE	S07-IRL-05115-01	64 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INTENTIONAL OVERDOSE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
COMPLETED SUICIDE	UNSPECIFIED INGREDIENT	S		ONCE		
POISONING	LIPOSTAT (PRAVASTATIN SODIUM) (PRAVASTATIN SODIUM)	C				
LEFT VENTRICULAR HYPERTROPHY	ZISPIN (MIRTAZAPINE) (MIRTAZAPINE)	C				
ARTERIOSCLEROSIS CORONARY ARTERY						
BRONCHOPNEUMONIA						
HEPATIC STEATOSIS						
PULMONARY OEDEMA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Apr-2009	6982158	EXPEDITED (15-DAY)	Y	DE	US-WATSON-2009-02802	25 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Toxicity to various agents	TEMAZEPAM	S		UNK		WATSON
	LEXAPRO	S		UNK		
	AMBIEN	S		UNK		
	ZYPREXA	S		UNK		
	ALCOHOL	S		UNK		
	DEXTROMETHORPHAN HYDROBROMIDE	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-May-2009	6992566	DIRECT	N	DE		54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANXIETY	LEXAPRO	S	ORAL	2-3/DAY PO		FOREST
NAUSEA	MIRTAZAPINE	S	ORAL	15MG AS NEEDED PO		
DECREASED APPETITE						
DYSPHAGIA						
FEAR						
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-May-2009	6993569	DIRECT		OT		51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INSOMNIA	LEXAPRO	S			6 DAY	
OBSESSIVE THOUGHTS						
SUICIDAL IDEATION						

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-May-2009	6897398	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009159452	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGGRESSION	CHANTIX	S		1 mg, 2x/day		PFIZER
ABNORMAL DREAMS	LEXAPRO	S		UNK		
	MECLIZINE	S		UNK		
	UNSPECIFIED INGREDIENT	S		UNK		
	FLEXERIL	C		UNK		
	KLONOPIN	C		UNK		
	COMPAZINE	C		UNK		
	SYNTHROID	C		UNK		
	LORTAB	C				
	AMANTADINE	C		UNK		
	FOLIC ACID	C		UNK		
	ZANAFLEX	C		UNK		
	FOSAMAX	C		UNK		
	METHOTREXATE	C		UNK		
	DEXTROSE	C		UNK		
	SOLU-MEDROL	C		UNK		
	COPAXONE	C		UNK		
	CALCIUM PHOSPHATE \ERGOCALCIFEROL	C		UNK		
	FLONASE	C				
	OXYBUTYNIN HYDROCHLORIDE	C		UNK		
	LISINOPRIL	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-May-2009	6987915	EXPEDITED (15-DAY)	N	OT	PHEH2009US04143	53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONFUSIONAL STATE	RECLAST	S		UNK		NOVARTIS
TINNITUS	LEXAPRO	S	ORAL	10 mg, QD		
NAUSEA	LEXAPRO	S	ORAL	20 mg, QD		
DIZZINESS	LEXAPRO	S	ORAL	10 mg QD x 7 days		
DISTURBANCE IN ATTENTION	LEXAPRO	S	ORAL	10 mg every other day x 7 days		
PARAESTHESIA	LEXAPRO	S	ORAL	10 mg, QOD	8 DAY	
	WELLBUTRIN	C		UNK		
	XANAX	C		UNK		
	CALCIUM	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-May-2009	6989198	EXPEDITED (15-DAY)	N	OT	US-KINGPHARMUSA00001-K200900500		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEHYDRATION	ALTACE	S				KING
ALANINE AMINOTRANSFERASE INCREASED	LOVENOX	S				
ASPARTATE AMINOTRANSFERASE INCREASED	AMLODIPINE	S				
HYPOTENSION	LEXAPRO	S				
DIARRHOEA	PREDNISONE	S				
FATIGUE	CEDIRANIB	S	ORAL	20 mg, qd	64 DAY	
LIVER FUNCTION TEST ABNORMAL	CEDIRANIB	S	ORAL	10 mg, qd		
	METFORMIN HYDROCHLORIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-May-2009	6994010	DIRECT	N	OT		53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIARRHOEA	LEXAPRO	S		20 MG 1 TABLET EVERY NIGHT AT BEDTIME, ONCE		
ASTHENIA						
DIZZINESS						
HYPERHIDROSIS						
NAUSEA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-May-2009	6994982	EXPEDITED (15-DAY)	N	DE	1000006099	62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEATH	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-May-2009	6910195	EXPEDITED (15-DAY)	N	HO	PHEH2009US01490	51 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSARTHRIA	CLONAZEPAM	S		0.5 mg, QID		
HYPERTENSION	INDERAL	C		UNK		
DRUG INTERACTION	LOTENSIN	C		UNK		
	ALLEGRA-D	C				
	RITALIN	S		Unk, Unk		NOVARTIS
	LEXAPRO	S	ORAL	10 mg daily		
	LEXAPRO	S	ORAL	20mg daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-May-2009	6996101	EXPEDITED (15-DAY)	Y	DE	1000006075		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC ARREST	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-May-2009	6991001	EXPEDITED (15-DAY)	Y	OT	US-JNJFOC-20090501180	29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
STRABISMUS	FLEXERIL	S				
DIPLOPIA	FLEXERIL	S				
	LEXAPRO	S				
	LEXAPRO	S				
	COGENTIN	S				
	COGENTIN	S				
	SEROQUEL	S				
	SEROQUEL	S				
	ABILIFY	S				
	ABILIFY	S				
	VISTARIL	S				
	VISTARIL	S				
	LAMICTAL	S				
	LAMICTAL	S				
	ALBUTEROL INHALERS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-May-2009	6991537	EXPEDITED (15-DAY)	Y	HO	US-WYE-H09179309	40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MOVEMENT DISORDER	PRISTIQ EXTENDED RELEASE	S	ORAL	unknown		WYETH
FATIGUE	LEXAPRO	S		unknown		LUNDBECK
Dysstasia						
EATING DISORDER						
INSOMNIA						
UNEVALUABLE EVENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-May-2009	6996175	DIRECT				49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANGINA PECTORIS	LEXAPRO	S				FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-May-2009	6996234	DIRECT	Y	OT		58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABDOMINAL DISCOMFORT	LEXAPRO	S	ORAL	20 MG ONCE DAILY PO		
ABDOMINAL PAIN	CITALOPRAM	S	ORAL	20 MG THREE TIMES DAILY PO		
ERUCTATION						
FLATULENCE						
MUSCLE SPASMS						
NAUSEA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-May-2009	6997765	DIRECT	Y	LT,OT		10 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABDOMINAL PAIN UPPER	LEXAPRO	S	ORAL	10MG ONCE DAILY PO		
VOMITING	PROZAC	S				
ABNORMAL BEHAVIOUR						
AGGRESSION						
HALLUCINATION						
MANIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-May-2009	6999254	DIRECT				28 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABDOMINAL DISCOMFORT	LEXAPRO	S	ORAL	10MG DAILY PO		
ASTHMA						
MUSCULOSKELETAL CHEST PAIN						
NAUSEA						
SOMNOLENCE						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-May-2009	7001388	DIRECT	N	OT		37 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING JITTERY	ZOLOFT	S		50		
BURNING SENSATION	LEXAPRO	S		10		
ANXIETY						
DECREASED APPETITE						
FEELING ABNORMAL						
INSOMNIA						
MENTAL DISORDER						
UNEVALUABLE EVENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-May-2009	7003232	EXPEDITED (15-DAY)	Y	HO	1000006183	82 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NEUROPATHY PERIPHERAL	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ABASIA	ARICEPT	C				
Dysstasia	LEVOTHYROXINE	C				
	LISINOPRIL	C				
	VIVELLE DOT	C				
	CLONIDINE	C				
	NAMENDA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-May-2009	6980337	EXPEDITED (15-DAY)	N	HO	1000005842	67 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TRANSIENT ISCHAEMIC ATTACK	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
FALL	METOPROLOL SUCCINATE	C				
DEHYDRATION						
UPPER LIMB FRACTURE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-May-2009	7003461	DIRECT	N	LT,OT,RI		51 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEADACHE	LEXAPRO	S	ORAL	1 DAILY PO		FOREST
DIZZINESS						
FAMILY STRESS						
LOSS OF EMPLOYMENT						
NAUSEA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-May-2009	7006163	EXPEDITED (15-DAY)	Y	DE,OT	1000006190	67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEPATIC ENZYME INCREASED	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-May-2009	7006659	EXPEDITED (15-DAY)	Y	OT	1000006217		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEART RATE INCREASED	LEXAPRO	S				
AFFECTIVE DISORDER						
DYSKINESIA						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-May-2009	7005331	DIRECT	N	OT		52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME	EFFEXOR XR	S	ORAL	150 MG. 2 TIMES A DAY PO SEVERAL YEARS		
IMPAIRED WORK ABILITY	LEXAPRO	S	ORAL	20 MG. 2 AT BEDTIME PO SEVERAL YEARS		FOREST
CONFUSIONAL STATE						
DEPRESSED MOOD						
DYSTONIA						
FATIGUE						
HOT FLUSH						
HYPERHIDROSIS						
INFLUENZA LIKE ILLNESS						
INSOMNIA						
MEMORY IMPAIRMENT						
MUSCULAR WEAKNESS						
MYALGIA						
NAUSEA						
PARAESTHESIA						
TEARFULNESS						
VOMITING						
WEIGHT DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-May-2009	7005519	DIRECT	Y			39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HOT FLUSH	LEXAPRO	S	ORAL	1 DAILY PO		
ANXIETY	CELEXA	S	ORAL	1 DAILY PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-May-2009	7007566	DIRECT	N	OT		73 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLADDER DISORDER	LEXAPRO	S		5 MG (LIQUID) DAILY		
CONDITION AGGRAVATED						
ULCER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-May-2009	7009109	EXPEDITED (15-DAY)	N	OT	1000006285	30 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
APNOEA	LEXAPRO	S	TRANSPLACENTAL	20 MG (20 MG), TRANSPLACENTAL		
MIDDLE INSOMNIA	ALLERX	C				
HYPOVENTILATION						
IRRITABILITY						
Maternal drugs affecting foetus						
MUSCLE TWITCHING						
RESPIRATORY RATE INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-May-2009	7007383	DIRECT	N			41 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BRUXISM	LEXAPRO	S	ORAL	10 MG -1 PILL- DAILY PO		FOREST
EUPHORIC MOOD						
EYE MOVEMENT DISORDER						
HEADACHE						
INSOMNIA						
JAW DISORDER						
MUSCLE TWITCHING						
TIC						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-May-2009	7008971	DIRECT	N	LT,OT		43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMMUNICATION DISORDER	LEXAPRO	S	ORAL	20MG 1 X DAY PO		
SPEECH DISORDER	LEXAPRO	S	ORAL	10 MG 1 X DAY PO		
ACTIVITIES OF DAILY LIVING IMPAIRED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-May-2009	7009013	DIRECT	N	OT		42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	LEXAPRO	S	ORAL	20 MG 1 DAILY PO APPROX. FEB TO MAY 2009		
AGGRESSION	KLONOPIN	C				
NO THERAPEUTIC RESPONSE	LAMICTAL	C				
SUICIDAL IDEATION	ZANAFLEX	C				
CONDITION AGGRAVATED	DIOVAN HCT	C				
DEPRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-May-2009	6988364	EXPEDITED (15-DAY)	Y	HO	1000005939	19 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH ERYTHEMATOUS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DRUG ABUSE						
WHITE BLOOD CELL COUNT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2009	7016684	EXPEDITED (15-DAY)	Y	HO	1000006495	71 YR	Female	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME	LEXAPRO	S	ORAL	5 MG (5 MG,1 IN 1 D),ORAL ; 10 MG (10 MG,1 IN 1 D),ORAL		
LOSS OF CONSCIOUSNESS	SEROQUEL	C				
DIZZINESS	OMEPRAZOL (TABLETS)	C				
	FAMOTIDINE	C				
	METAMUCIL (TABLETS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jun-2009	7016501	EXPEDITED (15-DAY)	Y	DE	1000006541	43 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	10 MG, ORAL, 10 MG (10 MG, 1 IN 1 D), ORAL		
TREATMENT NONCOMPLIANCE	TRAZODONE HYDROCHLORIDE	C				
THERMAL BURN						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Jun-2009	7024609	DIRECT	N	OT		66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SCREAMING	LEXAPRO	S		LEXAPRO 10 MG 1X		FOREST
DIZZINESS	KLONOPIN	C				
ABNORMAL DREAMS						
AMNESIA						
ANHEDONIA						
ANXIETY						
CONFUSIONAL STATE						
DEPERSONALISATION						
EMOTIONAL DISORDER						
HYPOAESTHESIA						
LOSS OF EMPLOYMENT						
NERVOUS SYSTEM DISORDER						
PAIN IN EXTREMITY						
PRODUCT QUALITY ISSUE						
SOMNOLENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jun-2009	7018031	DIRECT	Y	OT		38 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AMNESIA	LEXAPRO	S	ORAL	20MG BID PO		
ABNORMAL BEHAVIOUR						
PERSONALITY CHANGE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jun-2009	7023032	EXPEDITED (15-DAY)	Y	HO	1000006593	82 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EPISTAXIS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
HAEMATOCHEZIA	COUMADIN	S				
SLEEP DISORDER	VITAMINS	C				
ANXIETY	ATENOLOL	C				
	AMLODIPINE	C				
	QUINAPRIL	C				
	DIGOXIN	C				
	HYZAAR	C				
	WELCHOL	C				
	GEMFIBROZIL	C				
	METFORMIN HYDROCHLORIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jun-2009	7013107	NON-EXPEDITED	N		A0743970A		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TACHYPHYLAXIS	WELLBUTRIN XL	S	ORAL	300MG Per day		GLAXOSMITHKLINE
SEXUAL DYSFUNCTION	LEXAPRO	S	UNKNOWN			
	C-PAP	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jun-2009	7013177	NON-EXPEDITED	N		A0752544A		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EXERCISE LACK OF	WELLBUTRIN XL	S	ORAL	150MG Twice per day		GLAXOSMITHKLINE
	LEXAPRO	S	ORAL	20MG Per day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jun-2009	7013222	NON-EXPEDITED	N		A0758554A	37 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	WELLBUTRIN XL	S	ORAL	300MG Per day	26 WEEK	GLAXOSMITHKLINE
	LEXAPRO	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jun-2009	7022630	DIRECT	N	OT		49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EJACULATION FAILURE	LEXAPRO	S	ORAL	10MG ONCE DAILY PO		
BURNING SENSATION						
CHEST PAIN						
DISTURBANCE IN ATTENTION						
FATIGUE						
HYPERHIDROSIS						
PAIN IN EXTREMITY						
PARAESTHESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jun-2009	6990685	EXPEDITED (15-DAY)	N	OT	1000006012	53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	LEXAPRO	S	ORAL	SEE IMAGE		
CORONARY ARTERY DISEASE	AMARYL	C				
CRYING	METOPROLOL SUCCINATE	C				
NERVOUSNESS	NORVASC	C				
ANXIETY	CRESTOR	C				
IRRITABILITY	LISINOPRIL	C				
SENSORY DISTURBANCE	ADVIL	C				
CORONARY ARTERY OCCLUSION						
PAIN IN EXTREMITY						
THERAPY CESSATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jun-2009	7025058	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-14661680	82 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HAEMATOCHEZIA	COUMADIN	S				BRISTOL MYERS SQUIBB
EPISTAXIS	LEXAPRO	S	ORAL			
SLEEP DISORDER	VITAMINS	C				
ANXIETY	ATENOLOL	C				
	AMLODIPINE	C				
	QUINAPRIL	C				
	DIGOXIN	C				
	HYZAAR	C		1 Df = 50/12.5mg		
	WELCHOL	C				
	GEMFIBROZIL	C				
	METFORMIN HYDROCHLORIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jun-2009	7030033	DIRECT	N	HO,LT,CA,RI		1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal drugs affecting foetus	LEXAPRO	S	ORAL	10 MG 1 DAILY PO		
ATRIAL SEPTAL DEFECT						
CONGENITAL PULMONARY HYPERTENSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Jun-2009	7033218	DIRECT	N			48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCULAR WEAKNESS	LEXAPRO	S	ORAL	15 MG 1X DAILY PO		
MUSCULOSKELETAL STIFFNESS						
NEURALGIA						
PAIN						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jun-2009	7035190	DIRECT	Y	HO,DS,LT,CA,OT,RI		20 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	GEODON	S		100 MG		
MALAISE	LEXAPRO	S		100MG		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jun-2009	7003809	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009215184		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FIBROMYALGIA	ZOLOFT	S				PFIZER
GASTROOESOPHAGEAL REFLUX DISEASE	LEXAPRO	S				
AGITATION						
ANXIETY						
BLADDER DISORDER						
DEPRESSION						
PAIN						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jun-2009	7056612	NON-EXPEDITED	N		SPV1-2009-00991	70 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRURITUS	VYVANSE	S	ORAL	20 MG, 1X/DAY:QD, ORAL		
RASH	LEXAPRO	S	ORAL	20 MG, 1X/DAY:QD, ORAL		
	CALCIUM (CALCIUM)	C				
	VITAMIN D NOS (VITAMIN D NOS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2009	6955720	EXPEDITED (15-DAY)	Y	OT	1000005185	21 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AMENORRHOEA	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL		
	LEXAPRO	S	ORAL	ORAL		
	ALPRAZOLAM	C				
	PSYCHOTROPICS (NOS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2009	6974766	EXPEDITED (15-DAY)	N	HO	1000005494	80 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HAEMATEMESIS	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
DECREASED APPETITE	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
DEPRESSION	ASPIRIN	S				
THROAT IRRITATION	NEXIUM	C				
	BENICAR	C				
	LABETALOL	C				
	GLYBURIDE	C				
	NORVASC	C				

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jun-2009	7039869	DIRECT	Y			35 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME	LEXAPRO	S	ORAL	20 MG QD PO		
DIZZINESS	DEPLIN	C				
VERTIGO	AMBIEN	C				
AGITATION						
ANXIETY						
DEPERSONALISATION						
DISTURBANCE IN ATTENTION						
HEADACHE						
IRRITABILITY						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Jun-2009	7032430	EXPEDITED (15-DAY)	Y		US-MYLANLABS-2009S1007640	68 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CHEST PAIN	ALPRAZOLAM	S	ORAL			ALPHAPHARM
DRUG WITHDRAWAL SYNDROME	ALPRAZOLAM	S	ORAL			ALPHAPHARM
CHILLS	ALPRAZOLAM	S	ORAL			ALPHAPHARM
DYSKINESIA	ALPRAZOLAM	S	ORAL			ALPHAPHARM
TREMOR	ALPRAZOLAM	S	ORAL			ALPHAPHARM
HEADACHE	ALPRAZOLAM	S	ORAL			ALPHAPHARM
WEIGHT DECREASED	ALPRAZOLAM	S	ORAL			ALPHAPHARM
ASTHENIA	ALPRAZOLAM	S	ORAL			ALPHAPHARM
MALAISE	ALPRAZOLAM	S	ORAL			ALPHAPHARM
NAUSEA	ALPRAZOLAM	S	ORAL			ALPHAPHARM
RETCHING	ALPRAZOLAM	S	ORAL			ALPHAPHARM
	ALPRAZOLAM	S	ORAL			ALPHAPHARM
	ALPRAZOLAM	S	ORAL			ALPHAPHARM
	ALPRAZOLAM	S	ORAL			ALPHAPHARM
	LEXAPRO	S	ORAL		6 MTH	ALPHAPHARM
	LIPITOR	C	ORAL			
	BENICAR	C	ORAL			
	RALOXIFENE	C	ORAL			
	SYNTHROID	C	ORAL			
	CIPRO	C				
	NITROFURANTOIN	C				
	AZITHROMYCIN	C				
	DOXYCYCLINE	C				
	OMEPRAZOLE	C				
	FOLIC ACID	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Jun-2009	7040965	DIRECT	N	RI		32 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ERECTILE DYSFUNCTION	LEXAPRO	S	ORAL	1 ONCE A DAY PO		FOREST
BLOOD TESTOSTERONE DECREASED						
LIBIDO DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jun-2009	6936419	EXPEDITED (15-DAY)	N	DE	1000004976	26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	(10 MG), ORAL		
ANXIETY						
ASPHYXIA						
DEPRESSION						
PAIN						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jun-2009	7041346	DIRECT	N	RI		44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALOPECIA	LEXAPRO	S	ORAL	15MG 1X DAY PO		
ANXIETY						
HAIR TEXTURE ABNORMAL						
PRODUCT LABEL ISSUE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2009	6806546	EXPEDITED (15-DAY)	Y	OT	1000001430	42 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL		
WEIGHT INCREASED	LEXAPRO	S	ORAL	30 MG (30 MG, 1 IN 1 D),ORAL		
Dry eye	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
VISUAL ACUITY REDUCED	WELLBUTRIN	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
EYE PAIN	WELLBUTRIN	C				
HEADACHE	ZOCOR	C				
MACULOPATHY	XANAX	C				
VITREOUS DISORDER	GABAPENTIN	C				
VISION BLURRED	TOPAMAX	C				
BLEPHARITIS	INDOMETHACIN	C				
CHORIORETINAL DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2009	7044593	DIRECT	Y	OT		42 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANIC ATTACK	LEXAPRO	S				
ANXIETY	PROZAC	S				
ABASIA						
DRY MOUTH						
HEADACHE						
HYPERHIDROSIS						
HYPERTENSION						
PALPITATIONS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2009	7045097	DIRECT	N	OT		41 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	LEXAPRO	S	ORAL	10 MG 1-DAY ORAL 15-20 DAYS		
AGGRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jun-2009	7036393	EXPEDITED (15-DAY)	N	HO	US-RB-017383-09	21 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MOOD SWINGS	SUBOXONE	S	SUBLINGUAL	Varying dose up to 12 mg daily		
	LEXAPRO	S	UNKNOWN	Unknown dose		
	LEXAPRO	S	UNKNOWN	Unknown dose		
	SEROQUEL	S	UNKNOWN	Unknown		
	SEROQUEL	S	UNKNOWN	Unknown		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jul-2009	7047868	DIRECT	N	HO,LT,RI		50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S		10 MG DAILY		
ANXIETY	LEXAPRO	S				
AGGRESSION						
AGITATION						
ANGER						
DEPRESSION						
EMOTIONAL DISORDER						
FEELING ABNORMAL						
GENERAL PHYSICAL HEALTH DETERIORATION						
HYPERTENSION						
PARTNER STRESS						
SEROTONIN SYNDROME						
THINKING ABNORMAL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jul-2009	7050339	EXPEDITED (15-DAY)	N	OT	1000007143	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BREAST CANCER IN SITU	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
BREAST PAIN	ALPRAZOLAM	C				
BREAST SWELLING	PREVACID	C				
BREAST CANCER RECURRENT	SINGULAIR	C				
Oestrogen receptor assay positive	ADVIL	C				
	MULTIVITAMINS	C				
	CALCIUM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jul-2009	6755074	EXPEDITED (15-DAY)	Y	HO	1000000679	31 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D), ORAL		
APNOEA						
HEADACHE						
INCONTINENCE						
LETHARGY						
NUCLEAR MAGNETIC RESONANCE IMAGING BRAIN ABNORMAL						
UNRESPONSIVE TO STIMULI						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jul-2009	7049235	DIRECT	N			29 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
THROAT TIGHTNESS	LEXAPRO	S		ONCE DAILY		FOREST
UNEVALUABLE EVENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2009	7071116	NON-EXPEDITED	N	OT	IMP_04346_2009		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AMNESIA	BUDEPRION	S		(300 MG)	6 YR	
HALLUCINATION	LAMOTRIGINE	S	ORAL	(400 MG ORAL)	6 YR	
DEPRESSION	PAROXETINE HYDROCHLORIDE	S	ORAL	(DF ORAL)		
SOMNOLENCE	CLONAZEPAM	S		(DF)		
	LEXAPRO	S		(DF)		
	INSULIN HUMAN	C				
	TIOTROPIUM	C				
	CLOPIDOGREL BISULFATE	C				
	SIMVASTATIN	C				
	BLOOD PRESSURE MEDICATION	C				
	APO-HYDROXYZINE /0058401/	C				
	METOPROLOL TARTRATE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2009	7054385	DIRECT	N	LT,OT		61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERTENSION	LEXAPRO	S	ORAL	10MG ONE PER DAY PO		FOREST
PALPITATIONS	HCTZ	C				
NERVOUS SYSTEM DISORDER	ANTENOLOL	C				
THINKING ABNORMAL	EFFEXOR	C				
MENTAL DISORDER	AVINZA	C				
DELIRIUM						
UNEVALUABLE EVENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2009	7054450	DIRECT	N	OT		45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALOPECIA	LEXAPRO	S		5MG 1 PER DAY		
EMOTIONAL DISTRESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2009	7055776	EXPEDITED (15-DAY)	N	HO	1000007199		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
THINKING ABNORMAL	LEXAPRO	S				
WITHDRAWAL SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jul-2009	7039129	EXPEDITED (15-DAY)	Y		1000006914	74 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OSTEOARTHRITIS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
RHEUMATOID FACTOR INCREASED	MIRTAZAPINE	C				
	DEANXIT (TABLETS)	C				
	MELITRACEN (TABLETS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jul-2009	7043415	EXPEDITED (15-DAY)	Y	OT	1000006931	71 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GRAND MAL CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1IN 1 D), ORAL		
	RISPERDAL (SOLUTION)	C				
	METFORMIN HYDROCHLORIDE	C				
	NIFEDIPINE	C				
	XIAOKE WAN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jul-2009	7054411	DIRECT	N			27 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLADDER PAIN	LEXAPRO	S	ORAL	10 MG 1 DAILY PO		
DYSURIA						
MICTURITION URGENCY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jul-2009	7055109	DIRECT	N			46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	LEXAPRO	S	ORAL	10MG 1 TIME A DAY PO		
ABNORMAL BEHAVIOUR						
SOMNOLENCE						
VISION BLURRED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2009	7055616	DIRECT	Y			21 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLEPHAROSPASM	LEXAPRO	S	ORAL	10 MG ONCE BEFORE SLEEP PO (THIS WAS MY FIRST DOSE)		
ABNORMAL SENSATION IN EYE						
AGITATION						
DRY MOUTH						
EAR DISCOMFORT						
EPIGASTRIC DISCOMFORT						
HEADACHE						
HEART RATE INCREASED						
HOT FLUSH						
HYPERHIDROSIS						
NASAL DISCOMFORT						
NAUSEA						
PARAESTHESIA						
SEDATION						
TREMOR						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2009	7055703	DIRECT	Y			20 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FRUSTRATION	LEXAPRO	S		NORMAL 1 DOSE		
SUICIDAL IDEATION	ATIVAN	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jul-2009	7049340	EXPEDITED (15-DAY)	Y	HO	AU-ROCHE-642670	48 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FLUSHING	VALIUM	S	ORAL			ROCHE
ABNORMAL SLEEP-RELATED EVENT	CODEINE PHOSPHATE \DOXYLAMINE	S	UNKNOWN			
MYDRIASIS	SEROQUEL	S	UNKNOWN			
SOMNAMBULISM	ZOLPIDEM TARTRATE	S	ORAL			
SOMNOLENCE	LEXAPRO	S	ORAL			
	ALCOHOL	S	UNKNOWN			
	CALTRATE	C		DRUG REPORTED AS: CALTRATE 600		
	FISH OIL	C		DRUG: FISH OIL (NOS)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jul-2009	7055989	DIRECT	N	HO,LT,OT		46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MIGRAINE	CYMBALTA	S	ORAL	60MG DAILY PO		
SUICIDAL IDEATION	LEXAPRO	S	ORAL	20MG DAILY PO		
DEPRESSION						
SUICIDE ATTEMPT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2009	7040688	EXPEDITED (15-DAY)	Y	OT	1000006924	48 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
RESPIRATORY TRACT INFECTION	MIANSERIN (10 MILLIGRAM)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2009	7062235	EXPEDITED (15-DAY)	Y	HO	1000007370	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FALL	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
WRIST FRACTURE	BENADRYL	S	ORAL	ORAL		
CONFUSIONAL STATE						
CONTUSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jul-2009	7065205	DIRECT		HO,OT		40 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PERSONALITY CHANGE	LEXAPRO	S	ORAL	10 MG 1 - DAILY ORAL		
AGGRESSION						
MANIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2009	7063598	DIRECT	Y			23 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	LEXAPRO	S	ORAL	10MG ONCE A DAY PO		
FATIGUE						
FEELING ABNORMAL						
LOSS OF LIBIDO						
MENORRHAGIA						
MENSTRUATION IRREGULAR						
PALPITATIONS						
SEDATION						
SEXUAL DYSFUNCTION						
SOMNOLENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2009	7064761	EXPEDITED (15-DAY)	N	OT	1000007519		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
IMPAIRED DRIVING ABILITY	LEXAPRO	S	ORAL	ORAL		
LEGAL PROBLEM						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2009	7064822	EXPEDITED (15-DAY)	Y	OT	1000005620	23 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CHEST PAIN	LEXAPRO	S	ORAL	5 MG (5 MG,1 IN 1 D),ORAL		
ANXIETY						
PLEURITIC PAIN						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jul-2009	7059583	NON-EXPEDITED	Y		US-AMGEN-KDL293623	87 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HAEMOGLOBIN DECREASED	PROCRIT	S	SUBCUTANEOUS			
FEELING ABNORMAL	LEXAPRO	S				
DYSPNOEA	LIPITOR	C				
FATIGUE	LASIX	C	ORAL			
RASH	UNSPECIFIED ANTIHYPERTENSIVE AGENT	C				
	AGRYLIN	C				
	ASPIRIN	C				
	CATAPRES-TTS	C				
	PLAVIX	C				
	ANTIVERT	C				
	NITROGLYCERIN	C				
	CLONIDINE	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Jul-2009	7068887	EXPEDITED (15-DAY)	N	DE	1000007672		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jul-2009	7064333	NON-EXPEDITED	N		US-ABBOTT-08P-163-0488056-00		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG SCREEN FALSE POSITIVE	NORVIR	S				
	LEXAPRO	S				
	ATAZANAVIR SULFATE	S				
	TRUVADA	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jul-2009	7071329	DIRECT	N	OT		48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	LEXAPRO	S		30 MG. ONCE A DAY		
IMPULSE-CONTROL DISORDER						
LIBIDO INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jul-2009	7073454	EXPEDITED (15-DAY)	Y	HO	1000007695	70 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S				
	BLOOD PRESSURE MEDICATION (NOS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jul-2009	7073513	EXPEDITED (15-DAY)	N	HO	1000007775	20 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
APHASIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1D), ORAL		
HEADACHE	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
MOVEMENT DISORDER	SPIRONOLACTONE	C				
MUSCULAR WEAKNESS	SYNTHROID	C				
	MIRCETTE	C				
	ALBUTEROL (INHALANT)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Aug-2009	6691894	EXPEDITED (15-DAY)	Y	OT	US-ASTRAZENECA-2008UW13210	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	SEROQUEL	S	ORAL		4 YR	
SUICIDE ATTEMPT	SEROQUEL	S	ORAL		4 YR	
SUICIDAL IDEATION	XANAX	S			4 YR	
PANCREATITIS	XANAX	S			4 YR	
RENAL FAILURE	XANAX	S			4 YR	
THYROID DISORDER	WELLBUTRIN	S			4 YR	
DISSOCIATIVE DISORDER	WELLBUTRIN	S			4 YR	
DISORIENTATION	LEXAPRO	S			3 YR	
ACTIVITIES OF DAILY LIVING IMPAIRED	LEXAPRO	S			3 YR	
DEPRESSION	RESTORIL	S			4 YR	
BLOOD CHOLESTEROL ABNORMAL	RESTORIL	S			4 YR	
BLOOD TRIGLYCERIDES ABNORMAL	CYMBALTA	S			4 YR	
SLEEP APNOEA SYNDROME	CYMBALTA	S			4 YR	
HYPERTENSION	ZOLOFT	S				
STRESS	NEURONTIN	S				

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PAIN	NEURONTIN	S				
MENTAL DISORDER	TRAZODONE HYDROCHLORIDE	S				
WEIGHT DECREASED	EFFEXOR	S				
SCREAMING	LISINOPRIL	C				
INSOMNIA	FENOFIBRATE	C				
HEADACHE	FENOFIBRATE	C				
HYPERHIDROSIS	LEVOTHYROXINE	C				
HALLUCINATION	AMBIEN	C				
BRUXISM	HYDROCHLOROTHIAZIDE	C				
ROAD TRAFFIC ACCIDENT	HYDROCODONE BITARTRATE AND ACETAMINOPHEN	C				
ANXIETY	CARISOPRODOL	C				
AMNESIA						
ANGER						
APHASIA						
ASBESTOSIS						
ATTENTION DEFICIT/HYPERACTIVITY DISORDER						
BLOOD CHOLESTEROL INCREASED						
CONSTIPATION						
CONVULSION						
Decreased appetite						
EMOTIONAL DISTRESS						
FEELING ABNORMAL						
GAIT DISTURBANCE						
HOSTILITY						
HYPOTHYROIDISM						
LETHARGY						
MUSCLE SPASMS						
MUSCLE TWITCHING						
NIGHTMARE						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PALLOR						
PANIC DISORDER						
PARANOIA						
PYREXIA						
REGURGITATION						
RESTLESS LEGS SYNDROME						
TACHYCARDIA						
TARDIVE DYSKINESIA						
TREATMENT NONCOMPLIANCE						
URINARY INCONTINENCE						
VOMITING						
WITHDRAWAL SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Aug-2009	7078987	DIRECT	N	OT		50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MENORRHAGIA	LEXAPRO	S	ORAL	1 TAB DAILY PO		
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Aug-2009	6986675	EXPEDITED (15-DAY)	Y	HO	IE-ABBOTT-09P-229-0571118-00		Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GASTROINTESTINAL HAEMORRHAGE	LEXAPRO	S	ORAL			
	NU-SEALS ASPIRIN	C				
	PERINDOPRIL	C				
	GLUCOPHAGE	C				
	LEVOTHYROXINE SODIUM	C				
	LANSOPRAZOLE	C				
	LACTULOSE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Aug-2009	7129951	DIRECT	N	HO,DS,CA		< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal drugs affecting foetus	LEXAPRO	S				
CLEFT LIP AND PALATE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Aug-2009	7081741	DIRECT	N	DE		41 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S				
GUN SHOT WOUND						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Aug-2009	7074178	EXPEDITED (15-DAY)	N	HO	A0800751A	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEPATITIS	LAMICTAL	S	UNKNOWN			GLAXOSMITHKLINE
	LEXAPRO	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Aug-2009	7081059	EXPEDITED (15-DAY)	N	HO	1000007936	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEPSIS	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
CHOLELITHIASIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Aug-2009	7081530	DIRECT	N	HO		21 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
APHASIA	LEXAPRO	S	ORAL	10MG DAILY MOUTH		
CLONUS	MIRCETTE	C				
	SPIRONOLACTONE	C				
	SYNTHROID	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Aug-2009	6919577	NON-EXPEDITED	N		A0759303A	71 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
THERAPEUTIC RESPONSE UNEXPECTED	PAXIL	S	UNKNOWN		7 YR	GLAXOSMITHKLINE
RASH	VALTREX	S	ORAL	1G Three times per day	1 WEEK	GLAXOSMITHKLINE
SKIN DISCOLOURATION	LEXAPRO	S				
CONDITION AGGRAVATED	COZAAR	C				
	ANTIDEPRESSANT	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Aug-2009	7066907	EXPEDITED (15-DAY)	Y	DE	US-SANOFI-SYNTHELABO-A03200903164	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GUN SHOT WOUND	AMBIEN CR	S	ORAL			
COMPLETED SUICIDE	LEXAPRO	S	UNKNOWN			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Aug-2009	7077896	EXPEDITED (15-DAY)	Y	HO	AU-ASTRAZENECA-2009SE06774	49 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SOMNAMBULISM	SEROQUEL	S	ORAL			
FLUSHING	ZOLPIDEM	S	ORAL		8 DAY	
MYDRIASIS	VALIUM	S	ORAL			
SOMNOLENCE	ALCOHOL	S				
	LEXAPRO	S	ORAL			
	CODEINE PHOSPHATE \DOXYLAMINE SUCCINATE	S				
	CALTRATE	C				
	FISH OIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Aug-2009	7097488	DIRECT	Y	DE		37 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	CELEXA	S		NOT PRESCRIBED FOR THE CLIENT		
TOXICITY TO VARIOUS AGENTS	LEXAPRO	S	ORAL	20 MG AT BEDTIME PO		
INTENTIONAL OVERDOSE	LAMICTAL	S				
SELF-MEDICATION	XANAX	S				
	GABAPENTIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Aug-2009	7085596	DIRECT	N	DS		42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
THINKING ABNORMAL	CLONAZEPAM	S		1 ONCE DAILY		BARR
SUICIDAL IDEATION	LEXAPRO	S		1 ONCE DAILY		
FEELING ABNORMAL						
IMPRISONMENT						
VIOLENCE-RELATED SYMPTOM						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Aug-2009	7085971	DIRECT	N	DE		26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	ZOLOFT	S		200MG		
	LEXAPRO	S		10MG		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Aug-2009	7086337	DIRECT	N	RI		42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
IMPRISONMENT	CLONAZEPAM	S	ORAL	1 ONCE DAILY PO		
SUICIDAL IDEATION	LEXAPRO	S	ORAL	1 ONCE DAILY PO		
VIOLENCE-RELATED SYMPTOM						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Aug-2009	7096721	EXPEDITED (15-DAY)	Y	OT	1000006645	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONGENITAL PYELOCALIECTASIS	LEXAPRO	S	TRANSPLACENTAL	5 MG (5 MG, 1 IN 1 D), TRANSPLACENTAL, 5 MG (5 MG, 1 IN 1 D), TRANSAMMARY		
CAESAREAN SECTION	LEVOTHYROXINE	C				
HYDRONEPHROSIS	PRENATAL VITAMINS	C				
Maternal drugs affecting foetus	PULMICORT RESPULES	C				
EXPOSURE DURING BREAST FEEDING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Aug-2009	7007282	EXPEDITED (15-DAY)	Y	OT	1000006211	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HOT FLUSH	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL, 20 MG (20 MG, 1 IN 1 D), ORAL, 25 MG (25 MG, 1 IN 1 D), ORAL		
OVERDOSE	TAMOXIFEN CITRATE	S				
BREAST CANCER IN SITU	AMBIEN	C				
BREAST CANCER	ORAL CONTRACEPTIVES (NOS) (TABLETS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2009	7094796	EXPEDITED (15-DAY)	Y	OT	1000008145	43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
SUICIDAL IDEATION	KLONOPIN	S	ORAL	0.25 MG (0.25 MG, 1 IN 1 D), ORAL		
HOMICIDAL IDEATION	ALCOHOL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2009	7094902	EXPEDITED (15-DAY)	Y	OT	1000008126	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL		
	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
	TEGRETOL	C				
	ZONEGRAN	C				
	ALBUTEROL	C				
	ADVAIR HFA	C				
	ELAVIL	C				
	CLARITIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Aug-2009	7095219	DIRECT	Y	OT		27 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRY MOUTH	LEXAPRO	S	ORAL	10 MG AT BEDTIME PO		
ANXIETY						
DIARRHOEA						
DIZZINESS						
EYE DISORDER						
FORMICATION						
HYPERHIDROSIS						
INSOMNIA						
MYDRIASIS						
TACHYCARDIA						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Aug-2009	7095544	DIRECT	Y	HO		33 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANIC REACTION	LEXAPRO	S	ORAL	10MG QDAY PO		
CHEST PAIN	BUSPAR	C				
DELUSION	TRAZODONE HYDROCHLORIDE	C				
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Aug-2009	7084714	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14407712	24 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG SCREEN FALSE POSITIVE	REYATAZ	S				BRISTOL MYERS SQUIBB
	NORVIR	S				
	TRUVADA	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Aug-2009	7085368	EXPEDITED (15-DAY)	N	OT	A0802683A	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANOSMIA	WELLBUTRIN	S				GLAXOSMITHKLINE
	LEXAPRO	S	ORAL	20MG Per day		
	VERAPAMIL HYDROCHLORIDE	C				
	HYDROCHLOROTHIAZIDE	C				
	PRILOSEC	C				GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Aug-2009	7100202	EXPEDITED (15-DAY)	N	CA,OT	1000008263	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TALIPES	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
CRANIOSYNOSTOSIS	PAXIL	S	TRANSPLACENTAL	TRANSPLACENTAL		
ATRIAL SEPTAL DEFECT						
CONGENITAL ANOMALY						
DEVELOPMENTAL DELAY						
INJURY						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Aug-2009	7097833	DIRECT	N	OT		17 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	LEXAPRO	S	ORAL	ONE TABLET DAILY PO		
ABNORMAL BEHAVIOUR						
ALOPECIA						
AMNESIA						
ANGER						
IMPULSE-CONTROL DISORDER						
TRICHOTILLOMANIA						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Aug-2009	7098536	DIRECT	N	OT		34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SOMNOLENCE	LEXAPRO	S	ORAL	2.5 MG ONCE DAILY, AM PO		FOREST
COGNITIVE DISORDER						
CONTUSION						
DISCOMFORT						
FALL						
FATIGUE						
HYPOTENSION						
IMPAIRED WORK ABILITY						
MUSCULOSKELETAL STIFFNESS						
PRURITUS						
URTICARIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Aug-2009	7084009	EXPEDITED (15-DAY)	N	OT	1000007893	47 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANGLE CLOSURE GLAUCOMA	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
HEADACHE	LAMICTAL	C				
Nystagmus	ABILIFY	C				
RESTLESS LEGS SYNDROME	ALBUTEROL (AEROSOL FOR INHALATION)	C				
DIZZINESS	ALLEGRA	C				
ASTHENIA						
DISEASE RECURRENCE						
DRY MOUTH						
EYE MOVEMENT DISORDER						
FATIGUE						
FEELING HOT						
PALLOR						
PERIPHERAL COLDNESS						
TACHYCARDIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Aug-2009	7096260	NON-EXPEDITED	N		US-ABBOTT-08P-163-0484585-00	66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALOPECIA	SYNTHROID	S	ORAL			
	SYNTHROID	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S				
	ROSUVASTATIN CALCIUM	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Aug-2009	7108761	EXPEDITED (15-DAY)	Y	OT	1000008427	19 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CATARACT	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	SINGULAIR	C				
	FLONASE	C				
	SYNTHROID	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Aug-2009	7099491	EXPEDITED (15-DAY)	Y	OT	US-ROCHE-652008	43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	KLONOPIN	S	ORAL			ROCHE
SUICIDAL IDEATION	LEXAPRO	S	ORAL	OTHER INDICATION: ANXIETY		
HOMICIDAL IDEATION	ALCOHOL	S	UNKNOWN			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Sep-2009	7109398	DIRECT	N	RI		18 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG PER DAY PO	1 DAY	
AMNESIA						
ANXIETY						
BODY TEMPERATURE FLUCTUATION						
CHILLS						
Dry eye						
DRY MOUTH						
DYSPEPSIA						
FATIGUE						
FEAR						
FEELING ABNORMAL						
FORMICATION						
HALLUCINATION						
HEART RATE INCREASED						
HYPOAESTHESIA						
INFLUENZA LIKE ILLNESS						
INSOMNIA						
LOSS OF CONSCIOUSNESS						
MIGRAINE						
MUSCLE CONTRACTIONS INVOLUNTARY						
MYDRIASIS						
NAUSEA						
OROPHARYNGEAL PAIN						
PYREXIA						
RASH GENERALISED						
VISION BLURRED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Sep-2009	7110656	DIRECT	N	HO			Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	LEXAPRO	S		10 MG ONCE A DAY	3 DAY	
CRYING						
DIZZINESS						
FALL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Sep-2009	7082706	EXPEDITED (15-DAY)	Y	HO	1000007826	38 YR	Female	MYS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUPRAVENTRICULAR TACHYCARDIA	LEXAPRO	S	ORAL	30 MG (10 MG, 3 IN 1 D), ORAL; 20 MG (20 MG, 1 IN 1 D),ORAL		
	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	CLONAZEPAM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Sep-2009	7116254	DIRECT	N	OT		16 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	LEXAPRO	S	ORAL	20MG 2.5 TIMES PO		FOREST
INCORRECT DOSE ADMINISTERED						
OFF LABEL USE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2009	6906497	EXPEDITED (15-DAY)	Y	CA	1000003668		Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CLEFT LIP	LEXAPRO	S	TRANSPLACENTAL	SEE IMAGE		
CLEFT PALATE	LEVONELLE (TABLETS)	C				
MATERNAL CONDITION AFFECTING FOETUS	FOLIC ACID	C				
APGAR SCORE LOW						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2009	7125346	EXPEDITED (15-DAY)	N	OT	1000008691	35 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD ALCOHOL INCREASED	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
LEGAL PROBLEM	ALCOHOL	S		2 BEERS (ONCE)		
	LORZEPAM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Sep-2009	7096693	EXPEDITED (15-DAY)	Y	OT	1000007945	26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PARTIAL SEIZURES	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), PER ORAL		
FEELING ABNORMAL	YASMIN	C				
MALAISE	ALLERGY INJECTIONS (NOS)	C				
COLITIS ULCERATIVE						
FALL						
HYPERHIDROSIS						
MUSCULOSKELETAL STIFFNESS						
NAUSEA						
NUCLEAR MAGNETIC RESONANCE IMAGING BRAIN ABNORMAL						
TREMOR						
UNRESPONSIVE TO STIMULI						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Sep-2009	7117093	DIRECT	N			50 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANORGASMIA	LEXAPRO	S		10MG DAILY	6 DAY	FOREST
EJACULATION FAILURE	LEXAPRO	S		20MG DAILY	2 DAY	FOREST
GENITAL DISORDER MALE						
MALE ORGASMIC DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Sep-2009	7117198	DIRECT	N	DE		40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S			12 DAY	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Sep-2009	7133622	DIRECT	N			69 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSKINESIA	PRISTIQ EXTENDED RELEASE	S	ORAL	I DAILY PO	1 DAY	
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Sep-2009	6259219	EXPEDITED (15-DAY)	N	HO,OT	US-ASTRAZENECA-2006UW21906	39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVARIAN CYST	SEROQUEL	S	ORAL	100-200 MG	2 MTH	
DIABETES MELLITUS	SEROQUEL	S	ORAL	100-200 MG	2 MTH	
NEUROLEPTIC MALIGNANT SYNDROME	SEROQUEL	S	ORAL		1 MTH	
DIABETIC NEUROPATHY	SEROQUEL	S	ORAL		1 MTH	
DIABETIC NEPHROPATHY	SEROQUEL	S	ORAL	100 MG-200 MG		
BLOOD CHOLESTEROL INCREASED	SEROQUEL	S	ORAL	100 MG-200 MG		
HYPERLIPIDAEMIA	ABILIFY	S			1 YR	

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD TRIGLYCERIDES INCREASED	ABILIFY	S	ORAL			
	GEODON	S				
	GEODON	S		80 MG		
	RISPERDAL	S			17 MTH	
	RISPERDAL	S	ORAL			
	THORAZINE	S			1 YR	
	THORAZINE	S				
	PERPHENAZINE	S			1 YR	
	LEXAPRO	S				
	TRAZODONE HYDROCHLORIDE	S	ORAL	100 MG-150 MG	4 MTH	
	TRAZODONE HYDROCHLORIDE	S	ORAL	100 MG-150 MG	4 MTH	
	TRAZODONE HYDROCHLORIDE	S	ORAL	100 MG-150 MG		
	TRAZODONE HYDROCHLORIDE	S	ORAL	100 MG-150 MG		
	EFFEXOR	S	ORAL			
	PAXIL	S				
	ATIVAN	S				
	BUSPAR	S				
	AMITRIPTYLINE HYDROCHLORIDE \PERPHENAZINE	S				
	REMERON	S	ORAL			
	REMERON	S	ORAL			
	LAMICTAL	C	ORAL	25 MG-200 MG		
	LISINOPRIL	C		10 MG-20 MG		
	DETROL LA	C				
	CODEINE	C		300-30 MG, 1-2 TABLETS EVERY 4 TO 6 HOURS AS NEEDED		
	METRONIDAZOLE	C				
	NABUMETONE	C				
	PROZAC	C				
	WELLBUTRIN	C				

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	ZOLOFT	C				
	XANAX	C				
	GLUCOPHAGE	C	ORAL	500 MG-2000 MG		
	AVANDARYL	C	ORAL	4/2 MG		
	MOTRIN	C				
	ALBUTEROL	C		90 MCG INHALER		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2009	7117550	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14559165	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERHIDROSIS	MEGACE	S	ORAL	1 DF = 1 tab.2008-Jan09:1DF; Jan09:2 DF.		BRISTOL MYERS SQUIBB
DYSPEPSIA	LEXAPRO	S	ORAL	Nov08-Jan09:10mg;Jan09-24Feb09:20mg; 25Feb-10Mar:10mg; 11Mar:20mg.		
ABNORMAL DREAMS	LEXAPRO	S	ORAL	Nov08-Jan09:10mg;Jan09-24Feb09:20mg; 25Feb-10Mar:10mg; 11Mar:20mg.		
	XANAX	C				
	METOPROLOL TARTRATE	C				
	PERCOCET	C				
	CRESTOR	C				
	NEXIUM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2009	7117874	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009264035		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ADVERSE REACTION	XANAX	S				PFIZER
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2009	7136021	DIRECT	Y	DS		15 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRESYNCOPE	LEXAPRO	S				
UNRESPONSIVE TO STIMULI	XOPENEX HFA	S				
HYPERHIDROSIS	SINGULAIR	S				
BRADYCARDIA						
HEART RATE DECREASED						
PALLOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Sep-2009	7124849	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14372254	36 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	BUSPAR	S	ORAL	dose reduced to 10mg from oct2008		BRISTOL MYERS SQUIBB
AGITATION	KLONOPIN	C				
IRRITABILITY	BUSPAR	S	ORAL	dose reduced to 10mg from oct2008		BRISTOL MYERS SQUIBB
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Sep-2009	7077639	EXPEDITED (15-DAY)	Y	HO,OT	DSA_34038_2009		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERSENSITIVITY	CARDIZEM LA	S	ORAL	180 MG ORAL		
LOSS OF CONSCIOUSNESS	LEXAPRO	S	ORAL	DF; FREQUENCY QD ORAL		
GRAND MAL CONVULSION	REMERON	S	ORAL	DF ORAL		
SWELLING	VALIUM	C				
ABASIA	BENICAR	C				
APHASIA	TYLENOL	C				
VISION BLURRED	ARTIFICIAL TEARS	C				
ACIDOSIS						
ARRHYTHMIA						
ARTERIOSCLEROSIS CORONARY ARTERY						
BLOOD POTASSIUM DECREASED						
Dry eye						
ESSENTIAL HYPERTENSION						
FALL						
HYPOKALAEMIA						
HYPONATRAEMIA						
IRON DEFICIENCY ANAEMIA						
LEFT VENTRICULAR HYPERTROPHY						
MITRAL VALVE INCOMPETENCE						
PO2 DECREASED						
RENAL ARTERY ARTERIOSCLEROSIS						
SINUS TACHYCARDIA						
SYNCOPE						
TRICUSPID VALVE INCOMPETENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Sep-2009	6546132	EXPEDITED (15-DAY)	Y	HO,CA,OT	A0680992A	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TALIPES	PAXIL	S				GLAXOSMITHKLINE
ATRIAL SEPTAL DEFECT	LEXAPRO	S				
CONGENITAL ANOMALY						
CRANIOSYNOSTOSIS						
DEVELOPMENTAL DELAY						
Maternal exposure during pregnancy						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Sep-2009	7128826	NON-EXPEDITED	Y	OT	US-ASTRAZENECA-2009UW17939	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD GLUCOSE INCREASED	SEROQUEL	S	ORAL			
	LAMICTAL	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Sep-2009	7138874	DIRECT	N	OT		69 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREATMENT FAILURE	LEXAPRO	S		10 MG ONCE A DAY TAB		
DEPRESSION	CYMBALTA	C				
DIABETIC NEUROPATHY						
IRRITABILITY						
PAIN						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Sep-2009	7131505	EXPEDITED (15-DAY)		OT	PHEH2009US11016		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	TEKTURNA HCT	S		150/12.5 mg		NOVARTIS
DYSPHAGIA	METOPROLOL TARTRATE	S		50 mg, UNK		
FEELING HOT	LEXAPRO	S		10 mg, UNK		
DIZZINESS						
HEAD TITUBATION						
HYPERHIDROSIS						
HYPOAESTHESIA						
MUSCLE SPASMS						
VISION BLURRED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Sep-2009	7144089	EXPEDITED (15-DAY)	Y	DE	1000009056		Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Sep-2009	7138850	DIRECT	N	HO,DS,LT,OT,RI		40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AKATHISIA	LEXAPRO	S	ORAL	10 MG 1 X DAY PO		FOREST
DELUSION	CAMPRAL	S	ORAL	333 MG 3 X DAY PO		FOREST
ALCOHOL USE						
ANXIETY						
BLOOD PRESSURE INCREASED						
SUICIDE ATTEMPT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Sep-2009	7138854	DIRECT	Y	HO,LT,OT,RI		54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	LEXAPRO	S	ORAL	? ONCE A DAY PO	13 DAY	
DIVORCED	CELEBREX	S	ORAL	200MGS ONCE A DAY PO	8 YR	
ABDOMINAL PAIN UPPER						
ARTHRITIS						
CHEST PAIN						
DYSPNOEA EXERTIONAL						
FAMILY STRESS						
GASTROINTESTINAL DISORDER						
INSOMNIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Sep-2009	7141181	DIRECT	N	DS,RI		35 YR	Male	SGP

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MALE SEXUAL DYSFUNCTION	LEXAPRO	S		10MG DAILY		
ERECTILE DYSFUNCTION						
LOSS OF LIBIDO						
ORGANIC ERECTILE DYSFUNCTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Sep-2009	6258620	EXPEDITED (15-DAY)	Y	HO,OT	US-ASTRAZENECA-2006UW25940	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MOOD SWINGS	SEROQUEL	S	ORAL			
DEPRESSION	SEROQUEL	S	ORAL			
BIPOLAR DISORDER	SEROQUEL	S	ORAL	20-425 MG		
SCHIZOPHRENIA	SEROQUEL	S	ORAL	20-425 MG		
BIPOLAR I DISORDER	ABILIFY	S	ORAL			

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SCHIZOAFFECTIVE DISORDER BIPOLAR TYPE	HALDOL	S				
SCHIZOAFFECTIVE DISORDER	NAVANE	S				
MAJOR DEPRESSION	RISPERDAL	S	ORAL			
SCHIZOPHRENIA, PARANOID TYPE	THORAZINE	S				
HOMICIDAL IDEATION	ZYPREXA	S	ORAL	10-20 MG		
SUICIDAL IDEATION	ZYPREXA	S	ORAL	10-20 MG		
PSYCHOTIC DISORDER	LITHIUM	S				
HYPERGLYCAEMIA	PAXIL	S				
ASTHENIA	LEXAPRO	S	ORAL	10-20 MG		
DIABETES MELLITUS INADEQUATE CONTROL	COGENTIN	S				
SUICIDE ATTEMPT	DEPAKOTE	C	ORAL			
TACHYPHRENIA	NPH INSULIN	C		50 UNITS/44 UNITS, 30 UNITS/15 UNITS		
DIABETES MELLITUS	HUMULIN 70/30	C	SUBCUTANEOUS	40 UNITS EVERY MORNING/30 UNITS EVERY EVENING, 70 UNITS		
HALLUCINATION, AUDITORY	GLUCOTROL	C	ORAL			
	AVANDIA	C	ORAL			
	TRILEPTAL	C	ORAL			
	TYLENOL WITH CODEINE	C		EVERY 6 HRS		
	TYLENOL	C	ORAL	650 MG EVERY 4 HRS		
	DILANTIN	C	ORAL			
	LOPRESSOR	C	ORAL	50-200 MG		
	ALBUTEROL	C		2 PUFFS EVERY 4-6 HRS		
	ALBUTEROL	C		2 PUFFS EVERY 4-6 HRS		
	MAVIK	C	ORAL			
	LASIX	C	ORAL	20-40 MG		
	SINGULAIR	C	ORAL			
	DESYREL	C				

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	CAPOTEN	C				
	BENAZEPRIL	C	ORAL			
	WELLBUTRIN	C	ORAL			
	BUSPAR	C	ORAL			
	ASPIRIN	C	ORAL	81-325 MG		
	ATIVAN	C				
	RESTORIL	C				
	KLONOPIN	C	ORAL	1-6 MG		
	GLUCOPHAGE	C		500-1500 MG		
	NITROGLYCERIN	C				
	FLUTICASONE	C		1250 MCG		
	ADVAIR DISKUS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Sep-2009	7134848	EXPEDITED (15-DAY)	N	HO	US-ASTRAZENECA-2009SE 14269	38 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	ZOMIG	S				
GASTRIC BYPASS	LEXAPRO	S				
TREMOR	AMITRIPTYLINE	S				
THYROID DISORDER	IMITREX	C				
MIGRAINE	SUBOXONE	C				
PYREXIA	POTASSIUM	C				
DELIRIUM	TESTOSTERONE	C				
ACCIDENTAL OVERDOSE	PROGESTERONE	C				
	ESTROGEN PATCH	C				
	LORAZEPAM	C				
	GABAPENTIN	C				
	HYDROCORTISONE	C				
	CYANOCOBALAMIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Oct-2009	7071818	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20090709765	36 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANXIETY	RISPERDAL	S	ORAL			
Meniscus injury	LEXAPRO	S	UNKNOWN			
OEDEMA PERIPHERAL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Oct-2009	7132504	EXPEDITED (15-DAY)	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-14791669	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE ATROPHY	ABILIFY	S	ORAL	Initial dose:2mg T AM and TT HS) Increased to 5mg(04Aug09)BID		
GAIT DISTURBANCE	ABILIFY	S	ORAL	Initial dose:2mg T AM and TT HS) Increased to 5mg(04Aug09)BID		
RESTLESSNESS	LEXAPRO	S				
FATIGUE						
HEPATIC PAIN						
HEPATOMEGALY						
MOOD SWINGS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Oct-2009	7150983	EXPEDITED (15-DAY)	N	OT	1000009135	34 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG,ONCE), ORAL		
AURA	FLONASE	C				
DISORIENTATION	ALLEGRA	C				
LOSS OF CONSCIOUSNESS	SINGULAIR	C				
HEADACHE	ALPRAZOLAN	C				
BACK PAIN						
POSTICTAL HEADACHE						
POSTICTAL STATE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Oct-2009	7079840	EXPEDITED (15-DAY)	Y	DE	1000007891	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
GUN SHOT WOUND	AMBIEN CR	S	ORAL	12.5 MG, AS REQUIRED, ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Oct-2009	7130517	EXPEDITED (15-DAY)	Y	DE	1000008781	64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	5 MG (5MG, 1 IN 1 D), ORAL		
NAUSEA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ABDOMINAL DISTENSION	CYMBALTA	S	ORAL	20 MG, ORAL		
DIARRHOEA	KLONOPIN	C				
STRESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Oct-2009	7148165	DIRECT	Y	HO		21 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VOMITING	LEXAPRO	S	ORAL	10 MG DAILY PO		
CHILLS						
MUSCLE SPASMS						
RESTLESSNESS						
SEROTONIN SYNDROME						
YAWNING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Oct-2009	7153868	EXPEDITED (15-DAY)	N	CA	1000009164	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONGENITAL PULMONARY VALVE ATRESIA	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus						
MULTIPLE CONGENITAL ABNORMALITIES						
PYLORIC STENOSIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Oct-2009	7151549	DIRECT	N	OT,RI		36 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERHIDROSIS	EFFEXOR	S				
INSOMNIA	LEXAPRO	S				
IRRITABILITY	ZOLOFT	S				
ANTISOCIAL BEHAVIOUR						
DISTURBANCE IN ATTENTION						
FEELING ABNORMAL						
PHOBIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	6890107	NON-EXPEDITED	N	OT	1000003170	31 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VITAMIN D DEFICIENCY	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	6974767	NON-EXPEDITED	N	OT	1000005699	29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSPNOEA	LEXAPRO	S		10 MG (10 MG, 1 IN 1 D)		
ABDOMINAL PAIN						
CHEST PAIN						
CLUMSINESS						
CONSTIPATION						
CONVULSION						
DIZZINESS						
FATIGUE						
NAUSEA						
SPEECH DISORDER						
TRANSIENT ISCHAEMIC ATTACK						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7010348	NON-EXPEDITED	Y	OT	1000005861	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PLEURAL EFFUSION	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
LYMPHOCYTOSIS	DIOVAN	C				
	NORVASC	C				
	MELOXICAM	C				
	LOVASTATIN	C				
	NEXIUM	C				
	VITAMIN D	C				
	FLOMAX	C				
	XANAX	C				
	ALBUTEROL	C				
	FLONASE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7157201	EXPEDITED (15-DAY)	Y	OT	1000009302	21 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	ORAL		
BLOOD PRESSURE INCREASED	SYMBYAX	S		6/25 MG		
ANXIETY	WELLBUTRIN	S	ORAL	ORAL		
DEPRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7169611	NON-EXPEDITED	Y	HO	1000005454	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
URINARY TRACT INFECTION	LEXAPRO	S		10 MG (10 MG, 1 IN 1 D), 20 MG (20 MG, 1 IN 1 D)		
BLOOD SODIUM DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7169649	NON-EXPEDITED	N	HO	1000005925	16 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL, 15 MG (15 MG, 1 IN 1 D), ORAL		
ANXIETY	PROZAC	C				
ABDOMINAL PAIN UPPER						
DIARRHOEA						
DRUG INEFFECTIVE						
EATING DISORDER						
FATIGUE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7169665	NON-EXPEDITED	N	HO	1000006110	79 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEART RATE INCREASED	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
TREMOR	XANAX	C				
PANIC ATTACK	NORTRIPTYLINE	C				
ABDOMINAL DISCOMFORT						
ANXIETY						
DECREASED APPETITE						
DEPRESSION						
DIARRHOEA						
DIZZINESS						
FATIGUE						
NAUSEA						
NERVOUSNESS						
RESTLESSNESS						
SOMNOLENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7169743	NON-EXPEDITED	N	OT	1000006486	23 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL, 5 MG (5 MG, 1 IN 1 D), ORAL		
	TOPROL XL	C				
	FLORINEF ACETATE	C				
	VITAMINS	C				
	PEPCID	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7169754	NON-EXPEDITED	N	OT	1000006581	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DELUSION	TOPROL XL	C				
ANGER	LIPITOR	C				
IRRITABILITY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7169775	NON-EXPEDITED	Y	OT	1000007130		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANCREATITIS	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7169777	NON-EXPEDITED	Y	OT	1000007144		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPONATRAEMIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7170029	NON-EXPEDITED	N	HO	1000007337	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD PRESSURE INCREASED	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
HEART RATE INCREASED	LEXAPRO	S	ORAL	2.5 MG (2.5 MG, 1 IN 1 D), ORAL		
DYSPNOEA	ALPRAZOLAM	C				
SOMNOLENCE	COMBIVENT	C				
ANXIETY						
DISORIENTATION						
FEELING JITTERY						
HYPOAESTHESIA						
NERVOUSNESS						
PANIC ATTACK						
PARAESTHESIA						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7170031	NON-EXPEDITED	Y	HO	1000007702	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEPATITIS	LEXAPRO	S				
	LAMICTAL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7170039	NON-EXPEDITED	Y	OT	1000008086		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7170049	NON-EXPEDITED	N	OT	1000007480	75 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
FATIGUE	KADIAN	S	ORAL	100 MG (100 MG, 1 IN 1 D), ORAL		
	LISINOPRIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7170052	NON-EXPEDITED	N	OT	S07-USA-06169-01	26 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	40 MG (40 MG, 1 IN 1 D), ORAL		
ANXIETY	WELLBUTRIN	C				
AKATHISIA						
DEPRESSION						
OVERDOSE						
PARAESTHESIA						
SLEEP DISORDER						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7170119	NON-EXPEDITED	Y	DE,OT	1000007560	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEATH	LEXAPRO	S				
	ZYPREXA	S	ORAL	30 MG, ORAL		
	SYMBYAX	S		12/25MG (1 IN 1 D)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7170123	NON-EXPEDITED	N	HO	1000007706	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
NAUSEA	LAMICTAL	C				
INSOMNIA	CLONAZEPAM	C				
AGITATION	PRAVACHOL	C				
HEADACHE	ZETIA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7170124	NON-EXPEDITED	Y	OT	1000005617		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRIAPISM	LEXAPRO	S				
	SEROQUEL	C				
	VIAGRA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7172700	NON-EXPEDITED	Y	HO,LT,OT	S08-USA-02237-01	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANAPHYLACTIC REACTION	LEXAPRO	S	ORAL	20 MG (1 IN 1 D), ORAL : 30 MG (30 MG, DAILY), ORAL		
DRUG HYPERSENSITIVITY	UNSPECIFIED INGREDIENT	S				
OVERDOSE	CLONAZEPAM	C				
GASTROOESOPHAGEAL REFLUX DISEASE	INHALER	C				
RESPIRATORY TRACT INFECTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7174028	NON-EXPEDITED	Y	OT	1000000518		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANCREATITIS	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7174049	NON-EXPEDITED	N	OT	1000000839	40 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
PAIN	WELLBUTRIN	C				
ARTHRALGIA						
DEPRESSION						
FEELINGS OF WORTHLESSNESS						
HEADACHE						
INSOMNIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7174052	NON-EXPEDITED	Y	HO	1000000888	37 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL FIBRILLATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7174069	NON-EXPEDITED	Y	OT	1000001035	80 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD PRESSURE INCREASED	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
DIZZINESS	LANTUS	C				
AMNESIA	INSULIN NOS	C				
HOT FLUSH	NPH INSULIN	C				
FATIGUE	SYNTHROID	C				
INSOMNIA	LORAZEPAM	C				
HYPERHIDROSIS	DARVOCET	C				
DYSKINESIA	MECLIZINE	C				
TREMOR	MULTI-VITAMIN	C				
DRY MOUTH	SENOKOT	C				
	AVAPRO	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7174077	NON-EXPEDITED	Y	HO	1000001048	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SYNCOPE	LEXAPRO	S		20 MG (20 MG, QD)		
BRADYCARDIA	SUNITINIB	S		50 MG (QD)		
HYPOGLYCAEMIA	SORAFENIB	S		800 MG (400 MG, BID)		
	ACCUPRIL	S		40 MG (40 MG, QD)		
	OMACOR	S		4000 MG (1000 MG, QID)		
	COREG	S		12.5 MG (12.5 MG, QD)		
	HUMALOG	S		50 UNITS (25 UNITS QAM, 25 UNITS QPM)		
	HYDRALAZINE	S		25 MG, TID		
	NOVOLOG	S	SUBCUTANEOUS	(100 UNITS/ML TID), SUBCUTANEOUS		
	PRAVACHOL	S		40 MG (40 MG, QD)		
	ASPIRIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7174115	NON-EXPEDITED	N	OT	1000001143	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	SEE IMAGE		
OVERDOSE	XANAX	C				
BLOOD TRIGLYCERIDES INCREASED						
DIZZINESS						
HEADACHE						
HYPERHIDROSIS						
MUSCLE SPASMS						
NAUSEA						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7174121	NON-EXPEDITED	Y	OT	1000001199		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (DAILY), ORAL : 20 MG (DAILY), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7174122	NON-EXPEDITED	Y	OT	1000001206		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7174123	NON-EXPEDITED	Y	HO	1000001222	66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LEUKOPENIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	ALBUTEROL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7175299	NON-EXPEDITED	Y	OT	1000001454	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GASTROINTESTINAL HAEMORRHAGE	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
	ACIPHEX	C				
	SYNTHROID	C				
	ZANTAC	C				
	TUMS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7175321	NON-EXPEDITED	N	OT	1000001288	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DEPRESSION	CHANTIX	S		DAILY		
FEELINGS OF WORTHLESSNESS	LEVOXYL	C				
IRRITABILITY	LISINOPRIL	C				
CRYING	SINGULAIR	C				
DIZZINESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7175329	NON-EXPEDITED	Y	OT	1000001321		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7175367	NON-EXPEDITED	Y	OT	1000001502	49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	DARVOCET-N 100	C				
	TRAZODONE HYDROCHLORIDE	C				
	FLONASE	C				
	ASTELIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7176979	NON-EXPEDITED	Y	OT	1000001591	21 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALANINE AMINOTRANSFERASE INCREASED	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ASPARTATE AMINOTRANSFERASE INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7177048	NON-EXPEDITED	Y	OT	1000001674	30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DRUG INTERACTION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 QOD), ORAL		
FOOD CRAVING	AMITRIPTYLINE	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
NAUSEA	TRAMADOL HYDROCHLORIDE	S	ORAL	50 MG (50 MG, 1 IN 1 D), ORAL		
VOMITING	FLEXERIL	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DECREASED APPETITE	PHENERGAN	C				
TREMOR	DARVOCET	C				
PRURITUS GENERALISED	PROPRANOLOL	C				
HEADACHE	METFORMIN HYDROCHLORIDE	C				
WEIGHT INCREASED	XANAX	C				
VISUAL IMPAIRMENT	SYNTHROID	C				
EYE MOVEMENT DISORDER	TRI-SPRINTEC	C				
	HYDROCHLOROTHIAZE	C				
	WELLBUTRIN XL	C				
	CENTRUM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7177057	NON-EXPEDITED	Y	OT	1000001737	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	WELLBUTRIN	C				
	SYNTHROID	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7177066	NON-EXPEDITED	N	HO	1000003058	86 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABDOMINAL PAIN UPPER	LEXAPRO	S	ORAL	1 IN 1 D, ORAL		
VOMITING	HYDROXYUREA	C				
	ATENOLOL	C				
	AMLODIPINE BESYLATE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7177087	NON-EXPEDITED	N	OT	1000003119		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	SEE IMAGE		
DEPRESSED MOOD						
DEPRESSION						
FEELING OF BODY TEMPERATURE CHANGE						
HYPERHIDROSIS						
INFLUENZA LIKE ILLNESS						
OVERDOSE						
PAIN						
PARAESTHESIA						
WITHDRAWAL SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7177090	NON-EXPEDITED	Y	HO	1000003177	48 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONFUSIONAL STATE	LEXAPRO	S	ORAL	ORAL		
ANXIETY	UNSPECIFIED INGREDIENT	S	ORAL	2400 MG (400 MG, 6 IN 1 D), ORAL		
	LAMOTRIGINE	C				
	LEVETIRACETAM	C				
	PHENYTOIN	C				
	QUETIAPINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7179025	NON-EXPEDITED	N	OT	1000003223	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
STRESS	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
Balance disorder	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
EATING DISORDER	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
CONFUSIONAL STATE						
PAIN						
TACHYPHRENIA						
TINNITUS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7179031	NON-EXPEDITED	Y	HO	1000003458	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL FIBRILLATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	TOPROL XL	C				
	CADUET	C				
	NEURONTIN	C				
	PROTONIX	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7179038	NON-EXPEDITED	Y	OT	1000003667	30 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL, 5 MG (5 MG, 1 IN 1 D), ORAL		
	HYDROXYCHLOROQUINE	C				
	PREDNISONE	C				
	AZATHIOPRINE	C				
	TRAMADOL HYDROCHLORIDE	C				
	LANTUS	C				
	CALCIUM WITH VITAMIN D (TABLETS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7179054	NON-EXPEDITED	Y	HO	1000004973	40 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL, 1 ONCE, ORAL, 30 MG (30 MG, 1 IN 1 D), ORAL		
OVERDOSE	UNSPECIFIED INGREDIENT	S		ONCE, HIGH DOSE		
HALLUCINATION, AUDITORY	TYLENOL	C				
	ALEVE	C				
	RISPERDAL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7179059	NON-EXPEDITED	Y	HO	1000004977		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD SODIUM DECREASED	LEXAPRO	S	ORAL	10 MG (1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7179061	NON-EXPEDITED	Y	HO	1000004993	38 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INSOMNIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
AGITATION						
ANXIETY						
HYPERTENSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7179070	NON-EXPEDITED	Y	HO	1000005024	21 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INTENTIONAL OVERDOSE	LEXAPRO	S	ORAL	20 DOSAGE FORMS, ONCE, ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7179082	NON-EXPEDITED	Y	HO	1000005208	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ELECTROCARDIOGRAM QT PROLONGED	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL, 40 MG (40 MG, 1 IN 1 D), ORAL		
BRADYCARDIA	LINACLOTIDE (CAPSULES)	C				
SYNCOPE	PREMPRO	C				
	LUNESTA	C				
	ALEVE	C				
	DULCOLAX (BISACODYL)	C				
	ZITHROMAX	C				
	OMNARIS (NASAL DROPS (INCLUDING NASAL SPRAY)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7179092	NON-EXPEDITED	Y	HO	1000005233	70 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GASTROINTESTINAL HAEMORRHAGE	LEXAPRO	S				
	ASPIRIN	S				
	NUMEROUS OTHER MEDICATIONS (NOS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7179147	NON-EXPEDITED	Y	OT	1000005381	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
	TRILEPTAL	S	ORAL	600 MG (600 MG), ORAL		
	GEODON	C				
	NEURONTIN	C				
	TRAZODONE HYDROCHLORIDE	C				
	VALIUM	C				
	ACIPHEX	C				
	MARINOL	C				
	MIRALAX	C				
	BONIVA	C				
	ENABLEX	C				
	COPAXONE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2009	7212251	NON-EXPEDITED	Y	HO	1000006570	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PLATELET COUNT DECREASED	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Oct-2009	7150174	EXPEDITED (15-DAY)	N	DE	US-ABBOTT-09P-163-0601310-00	28 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUBDURAL HAEMORRHAGE	VICODIN	S		5/500 mg		
OVERDOSE	LEXAPRO	S		10 mg or 20 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Oct-2009	7154973	DIRECT	Y	HO		< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR NEONATAL	WELLBUTRIN	S	ORAL	300MG DAILY PO DURING THE PREGNANCY	9 MTH	
Maternal drugs affecting foetus	LEXAPRO	S	ORAL	20 MG DAILY PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Oct-2009	7156387	DIRECT		HO,LT,OT		77 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONFUSIONAL STATE	LEXAPRO	S	ORAL	1 BEDTIME ORAL		
ASTHENIA						
BLOOD PHOSPHORUS ABNORMAL						
BLOOD POTASSIUM ABNORMAL						
CEREBRAL HAEMORRHAGE						
DECREASED ACTIVITY						
FALL						
GAIT DISTURBANCE						
HALLUCINATION						
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Oct-2009	7162552	EXPEDITED (15-DAY)	N	OT	1000009365	51 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NASAL POLYPS	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
MUCOUS MEMBRANE DISORDER	RAMIPRIL	C				
SINUS DISORDER	UROXATRAL	C				
INFLAMMATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Oct-2009	7162581	EXPEDITED (15-DAY)	N	OT	AUR-APL-2009-00828		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD PRESSURE INADEQUATELY CONTROLLED	LISINOPRIL	S				
AMNESIA	LEXAPRO	S				
CONVULSION	DEPAKOTE	S				
HEADACHE	OXYBUTYNIN	S				
BLOOD PRESSURE FLUCTUATION						
FALL						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Oct-2009	7107170	EXPEDITED (15-DAY)	Y	HO,OT	1000008390		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONGENITAL ANOMALY	LEXAPRO	S				
MATERNAL EXPOSURE DURING PREGNANCY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Oct-2009	7168678	EXPEDITED (15-DAY)	N	CA	1000009473	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANAL ATRESIA	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
CONGENITAL CYSTIC KIDNEY DISEASE						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Oct-2009	7171623	EXPEDITED (15-DAY)	Y	OT	1000009597		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S				
BLOOD PRESSURE FLUCTUATION	OXYBUTYNIN	S				
GAIT DISTURBANCE	LISINOPRIL	S				
FALL	DEPAKOTE	S				
AMNESIA						
HEADACHE						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Oct-2009	7172963	EXPEDITED (15-DAY)	Y	HO	DSU-2009-02216	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	BENICAR	S	ORAL	PER ORAL		
HYPOTENSION	TARKA	S	ORAL	4/240 MG,PER ORAL		
SHOCK	LEXAPRO	S	ORAL	PER ORAL		
ELECTROCARDIOGRAM CHANGE	UNSPECIFIED INGREDIENT	S				
ALCOHOL USE						
ATRIAL FIBRILLATION						
BLOOD CHLORIDE INCREASED						
BLOOD GLUCOSE INCREASED						
BLOOD POTASSIUM DECREASED						
ELECTROCARDIOGRAM QT PROLONGED						
ELECTROCARDIOGRAM T WAVE ABNORMAL						
MOOD SWINGS						
PCO2 DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Oct-2009	7173058	EXPEDITED (15-DAY)	Y	OT	1000009684		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERTENSIVE CRISIS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Oct-2009	7166231	DIRECT		OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
URTICARIA	BUPROPION HYDROCHLORIDE	S		150 MG ONE DAILY 9/12/10 FOR 3 1/2 WEEKS		
CONSTIPATION	LEXAPRO	S		10 MG ONE DAILY	3 YR	
ANORGASMIA						
SEXUAL DYSFUNCTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Oct-2009	7166248	DIRECT				57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEART RATE DECREASED	LEXAPRO	S		10 MG 1 A DAY		
CONDITION AGGRAVATED						
DRY MOUTH						
FATIGUE						
LOSS OF LIBIDO						
PALPITATIONS						
SEXUAL DYSFUNCTION						
TINNITUS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Oct-2009	7048689	EXPEDITED (15-DAY)	N	HO,DS,OT	1000006980	14 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL ; 20 MG (20 MG,1 IN 1 D),ORAL		
ACTIVITIES OF DAILY LIVING IMPAIRED						
ALANINE AMINOTRANSFERASE INCREASED						
ASPARTATE AMINOTRANSFERASE INCREASED						
ASPHYXIA						
AUTONOMIC NERVOUS SYSTEM IMBALANCE						
BLOOD GLUCOSE INCREASED						
BLOOD PH DECREASED						
BLOOD PRESSURE DECREASED						
BLOOD PRESSURE INCREASED						
Candida infection						
DISTURBANCE IN ATTENTION						
FEEDING DISORDER						
HEART RATE INCREASED						
HYPERHIDROSIS						
HYPOXIC-ISCHAEMIC ENCEPHALOPATHY						
MUSCLE SPASTICITY						
OVERDOSE						
PNEUMONIA						
PNEUMONIA ASPIRATION						
PO2 DECREASED						
PUPIL FIXED						
PYREXIA						
RESPIRATION ABNORMAL						
RESPIRATORY RATE INCREASED						
SPEECH DISORDER						
SUICIDE ATTEMPT						
TREATMENT NONCOMPLIANCE						
UNRESPONSIVE TO STIMULI						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Nov-2009	7179654	EXPEDITED (15-DAY)	N	DE	1000009795	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Nov-2009	7173138	DIRECT	Y	LT		15 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG DAILY PO		
AGGRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Nov-2009	7173145	DIRECT	Y	HO,OT		44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EMOTIONAL DISORDER	LEXAPRO	S	ORAL	10MG DAILY PO		
FLAT AFFECT	CYMBALTA	C				
ANHEDONIA	PAXIL	C				
TREMOR	WELLBUTRIN	C				
VISION BLURRED	SEROQUEL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Nov-2009	7177280	EXPEDITED (15-DAY)	N	OT	1000009737	62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ROAD TRAFFIC ACCIDENT	LEXAPRO	S	ORAL	20 MG, (20 MG, 1 IN 1 D), ORAL		
WRIST FRACTURE	HYDROCODONE	S	ORAL	ORAL		
DRUG INTERACTION	VALIUM	C				
SUICIDAL IDEATION						
THINKING ABNORMAL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Nov-2009	7181990	EXPEDITED (15-DAY)	Y	OT	1000009811	2 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AUTISM	LEXAPRO	S	TRANSPLACENTAL	60 MG (60 MG, 1 IN 1 D), TRANSPLACENTAL		
Maternal drugs affecting foetus	ACETAMINOPHEN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Nov-2009	7185139	EXPEDITED (15-DAY)	Y	HO	1000009793	52 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EPILEPSY	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
	SIMVASTATIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Nov-2009	7174958	DIRECT	Y	HO,LT		83 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREATMENT NONCOMPLIANCE	LEXAPRO	S	ORAL	10 MG DAILY IN AM PO		
ANXIETY	REMERON	S	ORAL	15 MG AND INCREASED TO 30MG DAILY AT NIGHT PO		
DEPRESSED LEVEL OF CONSCIOUSNESS						
DISTURBANCE IN ATTENTION						
HAEMORRHAGE						
INTENTIONAL SELF-INJURY						
MEMORY IMPAIRMENT						
RESTLESSNESS						
SUICIDE ATTEMPT						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Nov-2009	6753412	EXPEDITED (15-DAY)	Y	DE	1000000628	42 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ASPHYXIA						
DRUG LEVEL INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Nov-2009	7186408	EXPEDITED (15-DAY)	N	OT	1000009868	28 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
IMPRISONMENT	CELEXA	S	ORAL	(20 MG), ORAL		
SEXUAL ABUSE	LEXAPRO	S	ORAL	(10 MG), ORAL		
	RESTORIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Nov-2009	7109273	EXPEDITED (15-DAY)	Y	HO,OT	1000008366	7 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION NEONATAL	LEXAPRO	S	TRANSPLACENTAL	20 MG, TRANSPLACENTAL		
DRUG WITHDRAWAL SYNDROME NEONATAL Maternal drugs affecting foetus	PRENATABS FA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Nov-2009	7126919	EXPEDITED (15-DAY)	Y	DE	1000008707	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	MORE THAN 1O (ONCE); 20 MG (20 MG, 1 IN 1 D), ORAL		
Intentional overdose	OXYCONTIN	S	ORAL	(800 MG, ONCE); 160 MG (80 MD, 2 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Nov-2009	7197633	NON-EXPEDITED	N		1000008965	41 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VISUAL IMPAIRMENT	MILNACIPRAN HYDROCHLORIDE	S	ORAL	12.5 MG (12.5 MG, 1 IN 1 D), ORAL 25 MG (12.5 MG, 2 IN 1 D), ORAL 50 MG (25 MG, 2 IN 1 D), ORAL		
MOTION SICKNESS	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
FEELING HOT PALPITATIONS	WELLBUTRIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Nov-2009	7179057	DIRECT	Y	HO,LT		27 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CHOLELITHIASIS	LEXAPRO	S	ORAL	10MG 1X DAILY PO		FOREST
AUTOIMMUNE HEPATITIS						
AUTOIMMUNE PANCREATITIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Nov-2009	7116188	EXPEDITED (15-DAY)	Y	OT	1000008645	50 YR	Male	NIC

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D) ORAL		
PARKINSONISM	VALPROIC ACID	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Nov-2009	7192614	EXPEDITED (15-DAY)	Y	DE	1000009996		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Nov-2009	7194850	EXPEDITED (15-DAY)	Y	HO	1000009931	68 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COLITIS	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
RECTAL HAEMORRHAGE	XANAX	C				
	SINGULAIR	C				
	SIMVASTATIN	C				
	ADVAIR DISKUS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Nov-2009	7053993	EXPEDITED (15-DAY)	Y	OT	1000007097		Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE SPASMS	LEXAPRO	S	ORAL	0.2 ML (0.2 ML,1 IN 1 D),ORAL		
NAUSEA	OXAZEPAM	C				
VOMITING	TEMAZEPAM	C				
	ACETAMINOPHEN AND CODEINE	C				
	ONDSANSETRON (TABLETS)	C				
	ESOEMPRAZOLE (TABLETS)	C				
	ALPRAZOLAM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Nov-2009	7143254	EXPEDITED (15-DAY)	Y	HO,LT	1000008911	80 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GRAND MAL CONVULSION	LEXAPRO	S	ORAL	5 MG (5 MG,1 IN 1 D),ORAL		
SOMNOLENCE	INSULATARD	C				
COMA	ACETYLSALICYLIC ACID	C				
	EMCONCOR	C				
	ACTRAPID	C				
	PLAVIX	C				
	ZOCOR	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Nov-2009	7183093	DIRECT	Y			66 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PYREXIA	LEXAPRO	S	ORAL	ORAL		
MYALGIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Nov-2009	7196235	EXPEDITED (15-DAY)	Y	OT	1000010007	40 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG LEVEL INCREASED	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
	CLOZARIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Nov-2009	7183911	DIRECT	Y	HO		42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	MAXALT	S				
BLOOD PRESSURE INCREASED	LEXAPRO	S				
MYOCLONUS						
UNRESPONSIVE TO STIMULI						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Nov-2009	7183977	DIRECT				38 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S		1 TABLET 1 X DAILY		
FOOD CRAVING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Nov-2009	7198485	EXPEDITED (15-DAY)	Y	OT	1000010051	20 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Nov-2009	7198490	EXPEDITED (15-DAY)	Y	OT	1000010103		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MENINGIOMA	LEXAPRO	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Nov-2009	7181818	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-09P-163-0607783-00	28 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEXUAL ABUSE	LEXAPRO	S	ORAL			
IMPRISONMENT	CITALOPRAM HYDROBROMIDE	S	ORAL			
	CHLORMEZANONE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Nov-2009	7185322	DIRECT					Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	LEXAPRO	S		10 MILLIGRAMS		
ABNORMAL SENSATION IN EYE						
Balance disorder						
DYSKINESIA						
HYPERSENSITIVITY						
SLEEP DISORDER						
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Nov-2009	7183618	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2009-BP-13094BP	36 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	ZANTAC	S	ORAL	300 mg		BOEHRINGER INGELHEIM
	LEXAPRO	S	ORAL	10 mg		
	MELATONIN	C				
	CALTRATE	C				
	CALCIUM ASCORBATE	C				
	CENTRUM MULTIVITAMIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Nov-2009	7186251	DIRECT	N	OT		42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AKATHISIA	LEXAPRO	S	ORAL	1 TABLET 1X DAILY PO		
CRYING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Nov-2009	7186368	DIRECT	N	OT		23 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH ERYTHEMATOUS	LEXAPRO	S	ORAL	5MG ONE PER DAY PO		
RASH PRURITIC						

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Nov-2009	7184473	EXPEDITED (15-DAY)	N	HO	US-ASTRAZENECA-2009SE 26324		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	SEROQUEL	S	ORAL		1 DAY	ZENECA
SUICIDAL IDEATION	WELLBUTRIN	S	ORAL		1 DAY	
CONFUSIONAL STATE	LEXAPRO	S	ORAL		2 YR	
HYPOMANIA	LEXAPRO	S	ORAL		0 YR	
AGITATION	LEXAPRO	S	ORAL		7 DAY	
DIZZINESS	LEXAPRO	S	ORAL		25 MTH	
SWELLING FACE	LAMICTAL	S			0 YR	
AKATHISIA	LAMICTAL	S			0 YR	
	RISPERDAL	S	ORAL			
	ZYRTEC-D	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Nov-2009	7184985	EXPEDITED (15-DAY)		HO,OT	AU-PFIZER INC-2009282671	55 YR	Male	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	NARDIL	S	ORAL	60 mg, 1x/day	20 DAY	PFIZER
ANXIETY	ZIPRASIDONE HYDROCHLORIDE	S	ORAL	20 mg, 2x/day	81 DAY	PFIZER
BLOOD CREATINE PHOSPHOKINASE INCREASED	ZIPRASIDONE HYDROCHLORIDE	S				PFIZER
	LEXAPRO	S				
	OLANZAPINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Nov-2009	7187259	EXPEDITED (15-DAY)	N	HO	A0822180A		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LAMICTAL	S	UNKNOWN	300MG per day		GLAXOSMITHKLINE
HYPOMANIA	WELLBUTRIN	S	ORAL	150MG Per day	1 DAY	GLAXOSMITHKLINE
CONFUSIONAL STATE	LEXAPRO	S	ORAL	30MG Per day		
SWELLING FACE	SEROQUEL	S	ORAL		1 DAY	
DIZZINESS	RISPERDAL	S	ORAL	.5MG Twice per day		
AGITATION	ZYRTEC-D	C				GLAXOSMITHKLINE
AKATHISIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Nov-2009	6053413	EXPEDITED (15-DAY)	Y	OT	S06-IRL-01778-01	40 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL		
ELECTROLYTE IMBALANCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Nov-2009	7214590	EXPEDITED (15-DAY)	Y	OT	1000010202		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Nov-2009	7213423	EXPEDITED (15-DAY)	Y	OT	1000010336	40 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SWOLLEN TONGUE	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
CHEST PAIN	NEXIUM	C				
HYPERTENSION	ZOPICLONE	C				
DYSPHAGIA	LEVOMEPROMAZINE	C				
CONDITION AGGRAVATED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Nov-2009	7192632	EXPEDITED (15-DAY)	N	HO	US-KINGPHARMUSA00001-K200901465	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LEVOXYL	S	ORAL	137 mcg, qd		KING
ANXIETY DISORDER	ATENOLOL	C	ORAL	25 mg, qd		
RESTLESSNESS	LIPITOR	C	ORAL	10 mg, qd		
HYPERTHYROIDISM	CELEXA	C		20 mg, UNK		
HEART RATE INCREASED	ATIVAN	C		UNK	39 DAY	
BLOOD PRESSURE INCREASED	LEVOXYL	S	ORAL	75 mcg, qd	6 DAY	KING
	LEVOXYL	S	ORAL	100 mcg, qd	7 DAY	KING
	LEVOXYL	S	ORAL	125 mcg, qd	4 DAY	KING
	LEVOXYL	S	ORAL	137 mcg, qd		KING
	KLONOPIN	S	ORAL	1 mg, bid		
	KLONOPIN	S	ORAL	1.0 mg, qd		
	KLONOPIN	S	ORAL	0.5 mg, bid		
	KLONOPIN	S	ORAL	0.5 mg, qd		
	LEXAPRO	S	ORAL	20 mg, qd	25 DAY	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Dec-2009	7162570	EXPEDITED (15-DAY)	N	OT	1000005272	31 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SICK SINUS SYNDROME	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
HYPOAESTHESIA	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL ; 10 MG (10 MG,1 IN 1 D),ORAL		
PARAESTHESIA	ERYTHROMYCIN	C				
ARRHYTHMIA SUPRAVENTRICULAR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Dec-2009	7201430	DIRECT		OT		68 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S		20 MG 1 X DAY	7 YR	FOREST
OFF LABEL USE						
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Dec-2009	6550324	EXPEDITED (15-DAY)	Y	HO	S08-USA-00239-01	17 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TUBULOINTERSTITIAL NEPHRITIS	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL ; 20 MG (20 MG,ONCE A DAY),ORAL		
RENAL FAILURE ACUTE	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL		
DIARRHOEA	IBUPROFEN	C				
ANAEMIA	ALPRAZOLAM (ALPRAZOLAM) (TABLETS) (ALPRAZOLAM)	C				
EOSINOPHIL COUNT INCREASED						
EOSINOPHIL PERCENTAGE INCREASED						
FAECES DISCOLOURED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Dec-2009	6874029	EXPEDITED (15-DAY)	Y	OT	1000003213	29 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION, VISUAL	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
FEELING ABNORMAL						
SENSORY DISTURBANCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Dec-2009	7206943	DIRECT	N	OT		38 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	LEXAPRO	S				
ACTIVITIES OF DAILY LIVING IMPAIRED						
EDUCATIONAL PROBLEM						
NAUSEA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Dec-2009	7228909	EXPEDITED (15-DAY)	N	OT	1000010529	41 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BENIGN INTRACRANIAL HYPERTENSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
MIGRAINE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Dec-2009	7232564	EXPEDITED (15-DAY)	Y	OT	1000010519	22 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPORTS INJURY	LEXAPRO	S	ORAL	ORAL		
CONCUSSION						
EYE MOVEMENT DISORDER						
HEAD INJURY						
NECK INJURY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Dec-2009	7170086	EXPEDITED (15-DAY)	Y	OT	1000009581	30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERHIDROSIS	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
PALPITATIONS	LEXAPRO	S	ORAL	5 MG (5 MG,1 IN 1 D),ORAL		
MYDRIASIS	ALLEGRA	C				
SINUS TACHYCARDIA	MULTI-VITAMIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Dec-2009	7210754	EXPEDITED (15-DAY)	N	OT	A0834197A		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	PAXIL	S	ORAL			GLAXOSMITHKLINE
DIARRHOEA	WELLBUTRIN	S	ORAL			GLAXOSMITHKLINE
DRUG INEFFECTIVE	EFFEXOR XR	S	ORAL	75MG Per day		
	PRISTIQ EXTENDED RELEASE	S	ORAL	50MG Per day		
	LEXAPRO	S	UNKNOWN			
	PEXEVA	S	UNKNOWN			GLAXOSMITHKLINE
	ZOLOFT	S	UNKNOWN			
	CYMBALTA	S	UNKNOWN			
	PROZAC	S	UNKNOWN			
	VITAMINS	C				
	FISH OIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	6884744	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14378962	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING ABNORMAL	ABILIFY	S	ORAL		2 WEEK	
	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	6884855	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-14390819	23 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PREGNANCY	ABILIFY	S	ORAL		3 YR	
NORMAL NEWBORN	LEXAPRO	S	ORAL		3 YR	
	TYLENOL	C				
	PROVENTIL	C	INHALATION			
	PRENATABS FA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7214760	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14420889		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DECREASED APPETITE	ABILIFY	S				
DEPRESSION	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7214786	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-14427603		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7214796	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14429047	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOMANIA	PAMELOR	S				
	ABILIFY	S				
	ABILIFY	S				
	LEXAPRO	S				
	WELLBUTRIN	S				
	ECHINACEA, UNSPECIFIED	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7214802	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14430953	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OEDEMA PERIPHERAL	ABILIFY	S			2 WEEK	
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7214913	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14456891	26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AMNESIA	ABILIFY	S				
SOMNOLENCE	LEXAPRO	S				
FATIGUE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7215170	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14502660		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	ABILIFY	S				
FEELING ABNORMAL	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7215369	NON-EXPEDITED	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-14529184		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GESTATIONAL DIABETES	ABILIFY	S				
PREGNANCY	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7215398	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14533855	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INCONTINENCE	ABILIFY	S				
HYPERHIDROSIS	LEXAPRO	S				
MUSCLE TWITCHING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7215411	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14535322	12 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	ABILIFY	S	ORAL	initiated at 2mg every day, titrating upto 10mg at bed time. dose increased to 10mg qd		
PALLOR	LEXAPRO	S				
COUGH	AMOXICILLIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7215449	NON-EXPEDITED	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-14539753	14 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	ABILIFY	S	ORAL			
	ABILIFY	S	ORAL			
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7215457	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14540769	14 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	ABILIFY	S				
PERSONALITY CHANGE	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7215640	NON-EXPEDITED	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-14568091		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERSENSITIVITY	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7215707	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14579890	39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TARDIVE DYSKINESIA	ABILIFY	S		Taken 5mg also		
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7215733	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-14583942	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING ABNORMAL	LISINOPRIL	S				
SOMNOLENCE	ABILIFY	S		Took in the morning and also at night. Later the dose was switched to bedtime.	2 DAY	
LETHARGY	WELLBUTRIN SR	S				
ASTHENIA	LEXAPRO	S				
	XANAX	S		As needed		
	ANTIDEPRESSANT	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7215760	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14587950		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	ABILIFY	S	ORAL			
	ABILIFY	S	ORAL			
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7215852	NON-EXPEDITED	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-14602049		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANCREATITIS	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7216051	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14631832		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BURNING SENSATION	ABILIFY	S				
	CYMBALTA	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7216118	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14647598	22 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TARDIVE DYSKINESIA	ABILIFY	S				
TREMOR	LEXAPRO	S				
SPEECH DISORDER	TOPAMAX	C				
	DEPO-PROVERA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7216125	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14649461	54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSARTHRIA	ABILIFY	S	ORAL	taken for one month		
	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7216167	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14663140		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD GLUCOSE INCREASED	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7216197	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14668230		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSTONIA	ABILIFY	S		initial dose 2mg for 2weeks		
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7216299	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14688253	38 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRIAPISM	ABILIFY	S				
EJACULATION DELAYED	ABILIFY	S				
OVERDOSE	LEXAPRO	S	ORAL	10mg tab,10mg; 20mg (once daily), 30mg (once daily),Titrated to 40mg once daily.		
MEMORY IMPAIRMENT	LEXAPRO	S	ORAL	10mg tab,10mg; 20mg (once daily), 30mg (once daily),Titrated to 40mg once daily.		
AGGRESSION	TEGRETOL XR	C				
AGITATION	LOVAZA	C				
ANGER	LISINOPRIL	C				
	VYTORIN	C				
	VITAMIN D	C				
	ATENOLOL	C				
	TOPAMAX	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7216527	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14732283	8 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SKIN HYPERPIGMENTATION	ABILIFY	S	ORAL			
	ABILIFY	S	ORAL			
	LEXAPRO	S				
	TENEX	S		Tenex .5 Am.		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7216607	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14745012		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BIPOLAR DISORDER	LEXAPRO	S				
DRUG INEFFECTIVE	ABILIFY	S				
DRUG INTERACTION	TEGRETOL	S		300 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7216684	NON-EXPEDITED	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-14755821		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GRAND MAL CONVULSION	ABILIFY	S	ORAL		1 WEEK	
INSOMNIA	LEXAPRO	S				
FATIGUE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7216730	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14765259	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2009	7216792	NON-EXPEDITED	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-14780001		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2009	7234959	EXPEDITED (15-DAY)	Y	HO,OT	1000010474	22 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERSENSITIVITY	LEXAPRO	S		ORAL		
JOINT STIFFNESS						
OCULOGYRIC CRISIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2009	7236425	EXPEDITED (15-DAY)	Y	HO	1000010647	18 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
URINARY RETENTION	LEXAPRO	S	ORAL	(10 MG), ORAL		
	NUROFEN	C				
	PARACETAMOL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2009	7238416	EXPEDITED (15-DAY)	N	HO	1000010781	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SINUSITIS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL; 20 MG (20 MG, 1 IN 1 D), ORAL		
DEPRESSION	DEPAKOTE	S	ORAL	1000 MG (500 MG, 2 IN 1 D), ORAL		
BIPOLAR DISORDER	PROMETHAZINE	S	ORAL	25 MG (25 MG, 1 IN 1 DAY), ORAL		
ABDOMINAL DISCOMFORT	RISPERIDONE	S	ORAL	1 MG (1 MG, 1 IN 1 D), ORAL		
SEDATION	KLONOPIN	C				
SOMNOLENCE	ACTIVELLA	C				
INTRACRANIAL ANEURYSM						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2009	7238484	EXPEDITED (15-DAY)	N	DE,HO	1000009699	91 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSPHAGIA	LEXAPRO	S	ORAL	10 MG 910 MG, 1 IN 1 D), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL		
CONFUSIONAL STATE	CARVEDILOL	C				
AGITATION						
DELIRIUM						
DYSARTHRIA						
EXCORIATION						
FALL						
GENERAL PHYSICAL HEALTH DETERIORATION						
HALLUCINATION						
LACERATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2009	7238712	EXPEDITED (15-DAY)	N	OT	1000010774	40 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MEMORY IMPAIRMENT	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL; 20 MG (20 MG, 1 IIN 1 D), ORAL		
HYPERHIDROSIS	METFORMIN (TABLETS)	C				
WEIGHT INCREASED	METOPROLOL SUCCINATE RETARD	C				
FATIGUE						
FEELING ABNORMAL						
SLEEP DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Dec-2009	7224969	NON-EXPEDITED	N		US-ASTRAZENECA-2009SE06350	66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LIMB INJURY	CRESTOR	S	ORAL			ASTRAZENECA
HOT FLUSH	LEXAPRO	S	UNKNOWN			
NAUSEA	ATENOLOL	C				
HEADACHE	COUMADIN	C				
DIZZINESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Dec-2009	7229786	DIRECT	N	OT		55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MOTOR DYSFUNCTION	PAXIL	S				
IMPAIRED WORK ABILITY	LEXAPRO	S				
	PRISTIQ EXTENDED RELEASE	S				
	EFFEXOR	S				
	LAMICTAL	S				
	TOPAMAX	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Dec-2009	7225873	EXPEDITED (15-DAY)	Y	HO	AU-ASTRAZENECA-2009SE32268		Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal exposure during pregnancy	ATACAND	S	ORAL			
AMNIOTIC FLUID VOLUME DECREASED	UNSPECIFIED INGREDIENT	S				
	INSULIN NOS	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Dec-2009	7226580	NON-EXPEDITED			US-ASTRAZENECA-2009UW00302		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FAECES DISCOLOURED	CRESTOR	S	ORAL			ASTRAZENECA
	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2009	7229760	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2009-BP-14482BP	62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONSTIPATION	SPIRIVA	S	INHALATION	18 mcg		BOEHRINGER INGELHEIM
	LEXAPRO	S				
	ASA	C				
	CARTIA XT	C				
	PANTOPRAZOLE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Dec-2009	7232108	DIRECT	N	LT		31 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EMOTIONAL DISORDER	LEXAPRO	S	ORAL	10 MILIGRAMS ONCE DAILY PO		
CRYING						
DEPRESSION						
DIARRHOEA						
DISTURBANCE IN ATTENTION						
FEAR						
FEELING ABNORMAL						
GASTROINTESTINAL DISORDER						
MANIA						
RESTLESSNESS						
WEIGHT DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Dec-2009	7231931	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009313148	81 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINAL COLUMN STENOSIS	LIPITOR	S	ORAL	10 mg, 1x/day		PFIZER
HYPOACUSIS	LEXAPRO	S		UNK		
ARTHRITIS	CENTRUM SILVER	S		UNK		
SCOLIOSIS	ECOTRIN	C		81 mg, 1x/day		
ALOPECIA	CALCIUM	C		Frequency: 4x/day,		
TINNITUS	COENZYME Q10	C		UNK		
	D3-VICOTRAT	C		Unit Dose: 2000;		
	ERGOCALCIFEROL\ZEAXANTHIN	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Dec-2009	7235649	DIRECT	N	OT		40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	LEXAPRO	S	SUBLINGUAL	10 MG 1/DAY SL; 5 MG 1/DAY SL		
ABNORMAL SENSATION IN EYE						
ADRENAL DISORDER						
ANXIETY						
Balance disorder						
DYSKINESIA						
HYPERACUSIS						
INSOMNIA						
PANIC ATTACK						
PHOTOPHOBIA						
VISUAL IMPAIRMENT						

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Dec-2009	7223473	EXPEDITED (15-DAY)	Y	HO	1000009255	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
IDIOPATHIC THROMBOCYTOPENIC PURPURA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
INFLUENZA	PNEUMOVAX 23	C				
HYPOXIA	FLUVIRIN NOS	C				
DYSPNOEA	NEXIUM	C				
HEADACHE	XANAX	C				
HYPONATRAEMIA	ESTRADIOL	C				
ATELECTASIS	VALTREX	C				
BILE DUCT STONE	TRAZODONE HYDROCHLORIDE	C				
RADICULOPATHY	WELLBUTRIN XL	C				
BACK PAIN	COLACE	C				
FIBRIN D DIMER INCREASED	ESZOPICLONE	C				
BLOOD POTASSIUM DECREASED	ZOLPIDEM	C				
ABDOMINAL PAIN						
ALANINE AMINOTRANSFERASE INCREASED						
ASPARTATE AMINOTRANSFERASE INCREASED						
ASTHENIA						
BLOOD CALCIUM DECREASED						
BLOOD GLUCOSE INCREASED						
CHEST PAIN						
HAEMANGIOMA OF LIVER						
INJECTION SITE CELLULITIS						
INJECTION SITE THROMBOSIS						
LUNG INFECTION						
OSTEOARTHRITIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Jan-2010	7220935	EXPEDITED (15-DAY)	Y	OT	1000010346	32 YR	Female	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GALACTORRHOEA	LEXAPRO	S	ORAL	10 MG, ORAL		
HEART RATE INCREASED	SERTINDOLE	S	ORAL	4 MG, ORAL 8 MG, ORAL		
BREAST MASS	PAROXETINE HYDROCHLORIDE	C				
DIZZINESS	LOSEC	C				
BLOOD PRESSURE SYSTOLIC INCREASED						
FATIGUE						
PALLOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2010	7293254	DIRECT	Y	HO		29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEPATITIS CHOLESTATIC	LEXAPRO	S	ORAL	10 MG ONE DAILY ORAL 047	42 DAY	
ANXIETY						
COAGULOPATHY						
DEPRESSION						
INSOMNIA						
MENTAL STATUS CHANGES						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jan-2010	7252939	EXPEDITED (15-DAY)	N	DE	1000011056	15 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
MOOD SWINGS	ATIVAN	C				
GUN SHOT WOUND						
SELF-MEDICATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jan-2010	7244062	DIRECT	N	OT		56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEART RATE IRREGULAR	LEXAPRO	S	ORAL	1X DAILY PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jan-2010	7255202	EXPEDITED (15-DAY)	Y	HO	1000011123	22 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PNEUMONIA ASPIRATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jan-2010	7234376	EXPEDITED (15-DAY)	N	HO	US-ABBOTT-09P-163-0616023-00	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INTRACRANIAL ANEURYSM	DEPAKOTE	S	ORAL			
SEDATION	LEXAPRO	S	ORAL			
SINUSITIS	LEXAPRO	S	ORAL			
HEADACHE	PROMETHAZINE	S	ORAL			
DEPRESSION	RISPERIDONE	S	ORAL			
BIPOLAR DISORDER	KLONOPIN	C	ORAL			
ABDOMINAL DISCOMFORT	ACTIVELLA	C				
SOMNOLENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jan-2010	7256252	EXPEDITED (15-DAY)	Y	OT	1000011141	81 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEAFNESS UNILATERAL	LEXAPRO	S				
SPINAL COLUMN STENOSIS	LIPITOR	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ARTHRITIS	CENTRUM SILVER	C				
SCOLIOSIS	ECOTRIN	C				
ALOPECIA	CALCIUM	C				
TINNITUS	COENZYME Q10	C				
	D3-VICOTRAT	C				
	MULTI-VITAMIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jan-2010	7222194	EXPEDITED (15-DAY)	Y	HO	1000010427		Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AMNIOTIC FLUID VOLUME DECREASED	LEXAPRO	S	ORAL	ORAL		
PREGNANCY	ATACAND	C				
GESTATIONAL DIABETES	ELEVIT VITAMINS	C				
MATERNAL EXPOSURE DURING PREGNANCY	INSULIN NOS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2010	7223560	EXPEDITED (15-DAY)	Y	HO,CA	1000010428		Unknown	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RENAL FAILURE	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
NEPHROLITHIASIS	ATACAND	C				
AMNIOTIC FLUID VOLUME DECREASED	ELEVIT VITAMINS	C				
CONGENITAL BLADDER ANOMALY	INSULIN NOS	C				
FOETAL DISORDER						
Maternal drugs affecting foetus						
NEONATAL DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jan-2010	7247959	EXPEDITED (15-DAY)	Y	HO	US-RANBAXY-2010US-30334		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	ISOTRETINOIN	S	ORAL	20 mg, bid	30 DAY	RANBAXY
CONVULSION	ISOTRETINOIN	S	ORAL	20 mg, tid	96 DAY	RANBAXY
COMA	LEXAPRO	S	ORAL			
OVERDOSE	LEXAPRO	S	ORAL	UNK		
DISORIENTATION	CELEXA	S	ORAL	UNK	20 DAY	
	ULTRAM	S	ORAL	50 mg, UNK	1 DAY	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jan-2010	7247794	EXPEDITED (15-DAY)	Y	HO	1000010855	36 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ELECTROCARDIOGRAM QT PROLONGED	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
OVERDOSE	LEXAPRO	S	ORAL	>200 MG (ONCE), ORAL		
INTENTIONAL SELF-INJURY	LORAZEPAM	S	ORAL	0.5 MG (0.5 MG, 1 IN 1 D), ORAL		
ELECTROLYTE IMBALANCE	LORAZEPAM	S	ORAL	10 MG (ONCE), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jan-2010	7252976	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2010-BP-00734BP	68 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	SPIRIVA	S	INHALATION	18 mcg		BOEHRINGER INGELHEIM
IMPATIENCE	LIPITOR	S				
ANXIETY	ZYRTEC	S				
IRRITABILITY	ZETIA	S				
	LEXAPRO	S				
	HYDROCHLOROTHIAZIDE	C				
	LEVOTHYROXINE	C				
	AMBIEN	C				
	ESTRADIOL	C				
	TRAMADOL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jan-2010	7254868	EXPEDITED (15-DAY)	N	OT	1000011162	22 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BRADYCARDIA	LEXAPRO	S	ORAL	5 MG (5 MG,1 IN 1 D),ORAL		
CHEST PAIN						
DYSPNOEA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jan-2010	7274376	EXPEDITED (15-DAY)	Y	HO,OT	1000009675	37 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PHYSICAL ASSAULT	LEXAPRO	S		10 MG		
EMOTIONAL DISORDER						
HOMICIDE						
SUICIDE ATTEMPT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2010	7169675	EXPEDITED (15-DAY)	Y	OT	US-ABBOTT-09P-163-0605763-00		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	DEPAKOTE	S				
BLOOD PRESSURE FLUCTUATION	LEXAPRO	S				
GAIT DISTURBANCE	OXYBUTYNIN CHLORIDE	S				
FALL	LISINOPRIL	S				
AMNESIA						
HEADACHE						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2010	7283356	DIRECT					Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ADVERSE EVENT	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2010	7258804	NON-EXPEDITED	N		A0771217A	68 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INSOMNIA	WELLBUTRIN	S	ORAL	300MG Per day		GLAXOSMITHKLINE
HYPERHIDROSIS	LEXAPRO	S	ORAL	20MG Per day		
FATIGUE	MIRTAZAPINE	S	ORAL	15MG Per day		
	LORAZEPAM	C	ORAL	1MG Per day		
	TOPROL XL	C	ORAL	25MG Per day		
	ISOSORBIDE	C	ORAL	30MG Per day		
	GLIPIZIDE	C	ORAL	4MG Twice per day		
	METFORMIN HYDROCHLORIDE	C	ORAL	500MG Twice per day		GLAXOSMITHKLINE
	ALTACE	C	ORAL	10MG Per day		GLAXOSMITHKLINE
	LIPITOR	C	ORAL	10MG Per day		GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2010	7280984	EXPEDITED (15-DAY)		HO,OT	1000011453		Male	CHN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GASTRIC ULCER	LEXAPRO	S	ORAL	15 MG (15 MG, 1 IN 1 D), ORAL		
ABDOMINAL DISTENSION	DIAZEPAM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Feb-2010	7243448	EXPEDITED (15-DAY)	N	OT	1000010834	39 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GALACTORRHOEA	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL, 5 MG (5 MG, 1 IN 1 D), ORAL		
THROMBOCYTOPENIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
LEUKOPENIA	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
MASTITIS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
CONTUSION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
ARTHRALGIA						
BREAST TENDERNESS						
DIZZINESS						
OEDEMA PERIPHERAL						
PRURITUS GENERALISED						
PYREXIA						
RASH						
SYNCOPE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Feb-2010	7267031	NON-EXPEDITED	N		A0835418A	35 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CHEST PAIN	TREXIMET	S	ORAL	1TAB Single dose	1 DAY	GLAXOSMITHKLINE
VOMITING	LEXAPRO	S			5 YR	
CHEST DISCOMFORT						
DRUG INTERACTION						
FATIGUE						
FEELING ABNORMAL						
NAUSEA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2010	7301176	EXPEDITED (15-DAY)	Y	DE	1000011540	47 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEART RATE INCREASED	LEXAPRO	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2010	7257726	EXPEDITED (15-DAY)	Y	OT	1000011248	55 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ERYTHEMA MULTIFORME	LEXAPRO	S	ORAL	10 MG, (10 MG, 1 IN 1 D), ORAL		
Photosensitivity reaction	AMITRIPTYLINE	C				
	OXAZEPAM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2010	7295088	EXPEDITED (15-DAY)	N	DE	1000011542	25 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONDITION AGGRAVATED	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL		
COMPLETED SUICIDE						
DEPRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2010	7256593	EXPEDITED (15-DAY)	N	OT	1000011206	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LEGAL PROBLEM	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
	SOMA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2010	7277460	EXPEDITED (15-DAY)	Y	HO,OT	US-PFIZER INC-2010014376	66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	ZOLOFT	S				PFIZER
DECREASED APPETITE	PROPYLTHIOURACIL	S				
TREMOR	PRISTIQ EXTENDED RELEASE	S	ORAL	50 mg, 1x/day		
UNEVALUABLE EVENT	CIPROFLOXACIN	S				
DEPRESSED MOOD	LEVOTHYROXINE SODIUM	S				
NERVOUSNESS	LEXAPRO	S				
ACTIVITIES OF DAILY LIVING IMPAIRED	AMITRIPTYLINE	S				
CYSTITIS	PERPHENAZINE AND AMITRIPTYLINE HYDROCHLORIDE	S				
DRUG INTOLERANCE	KLONOPIN	C				
	SEROQUEL	C		12.5 mg, as needed		
	LEVOTHYROXINE	C		82 ug, 1x/day		
	AMLODIPINE	C				
	PROPRANOLOL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2010	7285024	DIRECT	Y	HO		35 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL FIBRILLATION	LEXAPRO	S	ORAL	10 MG ONCE DAILY PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2010	7385692	DIRECT	Y	HO,DS,LT,OT,RI		35 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
IMPAIRED GASTRIC EMPTYING	CYMBALTA	S	ORAL	60 MG PO DAILY	3 YR	
	LEXAPRO	S				
	GEODON	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2010	7280158	NON-EXPEDITED			US-ABBOTT-09P-163-0611316-00	69 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ERYTHEMA	SIMCOR	S		1000mg		
RASH	SIMCOR	S				
PRURITUS	SIMCOR	S				
BREAST MASS	LEXAPRO	S				
LOCAL SWELLING	PIOGLITAZONE HYDROCHLORIDE	C				
PAIN IN EXTREMITY	METOPROLOL TARTRATE	C				
HYPERSENSITIVITY	FUROSEMIDE	C				
HOT FLUSH	SITAGLIPTIN PHOSPHATE	C				
FEELING ABNORMAL	RANITIDINE	C				
	TOPAMAX	C				
	ASPIRIN	C				
	CENTRUM SILVER	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2010	7171550	EXPEDITED (15-DAY)	Y	OT	1000009564	18 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INTENTIONAL OVERDOSE	LEXAPRO	S	ORAL	(ONCE), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL		
TOXICITY TO VARIOUS AGENTS	BENXODIAZEPINE (TABLETS)	C				
PALPITATIONS	CANNABIS (TABLETS)	C				
ANXIETY						
POOR QUALITY SLEEP						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2010	7238459	EXPEDITED (15-DAY)	N	OT	1000010813	81 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERTENSION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
ATRIAL FIBRILLATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
CEREBROVASCULAR ACCIDENT	SYNTRHOID (100 MILLIGRAM)	C				
CHEST PAIN	MAALOX	C				
DYSPNOEA	VITAMIN B COMPLEX	C				
ABDOMINAL PAIN						
CONDITION AGGRAVATED						
CONSTIPATION						
COUGH						
HYPERHIDROSIS						
MUSCULOSKELETAL PAIN						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2010	7255216	EXPEDITED (15-DAY)	Y	OT	1000011083	72 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RETINAL HAEMORRHAGE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
MACULAR DEGENERATION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
DYSGEUSIA	COZAAR	C				
	TYLENOL	C				
	SYNTHROID	C				
	NEBULIZER	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2010	7303763	DIRECT	Y			49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALOPECIA	ISENTRESS	S	ORAL	400MG BID PO		
	LYRICA	S				
	LEXAPRO	S				
	LIPITOR	S				
	REQUIP	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2010	7308768	EXPEDITED (15-DAY)	N	HO	1000011740	38 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL FIBRILLATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL; 5 MG(5 MG 1 IN 1 D),ORAL		
FEELING COLD						
HOT FLUSH						
INFLUENZA LIKE ILLNESS						
INSOMNIA						
SUPRAVENTRICULAR EXTRASYSTOLES						
TACHYCARDIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2010	7225874	EXPEDITED (15-DAY)	Y	CA	AU-ASTRAZENECA-2009SE 32262	121 DAY	Unknown	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal exposure during pregnancy	ATACAND	S	TRANSPLACENTAL			
NEPHROLITHIASIS	MINERALS\VITAMINS	S	TRANSPLACENTAL			
RENAL FAILURE	INSULIN NOS	S	TRANSPLACENTAL			
	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2010	7313953	EXPEDITED (15-DAY)	Y	OT	1000011817	32 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	LEXAPRO	S	ORAL	5 MG 95 MG, 1 IN 1 D), ORAL, 10 MG (10 MG, 1 IN 1 D), ORAL		
RESTLESSNESS	CORTISON	C				
	CLONAZEPAM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2010	7101275	EXPEDITED (15-DAY)	Y	OT	1000008195	49 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GRAND MAL CONVULSION	LEXAPRO	S	ORAL	10 MG, ONCE, ORAL		
CEREBRAL CYST						
HALLUCINATION, VISUAL						
STRESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2010	7299902	DIRECT	N			50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INSOMNIA	LEXAPRO	S				
AGORAPHOBIA						
ANXIETY						
DIZZINESS						
DRUG INEFFECTIVE						
HYPERHIDROSIS						
IMPAIRED WORK ABILITY						
INCREASED APPETITE						
NAUSEA						
PANIC ATTACK						
PERSONALITY DISORDER						
PYREXIA						
SWOLLEN TONGUE						
VISION BLURRED						
VISUAL ACUITY REDUCED						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2010	7318916	EXPEDITED (15-DAY)	Y	DE,HO	1000011878	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
HERPES ZOSTER	ZYPREXA	S	ORAL	10 MG (10 MG,1 IN 1 D), ORAL		
TACHYCARDIA	FANAPT	S	ORAL	2 MG (1 MG,2 IN 1 D),ORAL		
RESPIRATORY ARREST	SONATA	C				
BRAIN DEATH						
COMA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2010	7292102	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010019849		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PERSONALITY DISORDER	CHANTIX	S	ORAL	UNK		PFIZER
AGITATION	LEXAPRO	S	ORAL	UNK		
ANGER						
DRUG INTERACTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2010	7302776	DIRECT		OT		38 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	LEXAPRO	S	ORAL	10 MG DAILY PO	8 MTH	
PRODUCT CONTAMINATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2010	7317648	DIRECT	N			52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	CITALOPRAM	S	ORAL	60 MG DAILY ORAL		MYLAN
NIGHTMARE	TRAZODONE HYDROCHLORIDE	S				
SOMNOLENCE	LEXAPRO	S				
DRUG WITHDRAWAL SYNDROME						
DYSPHONIA						
FATIGUE						
PRODUCT SUBSTITUTION ISSUE						

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2010	7319989	EXPEDITED (15-DAY)	N	OT	1000011845	43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG,ONCE), ORAL		
DIZZINESS	LAMICTAL (200 MILLIGRAM, TABLETS)	C				
CONFUSIONAL STATE	ARICEPT (1 MILLIGRAM, TABLETS)	C				
LETHARGY	XANAX (1 MILLIGRAM, TABLETS)	C				
	KEPPRA (500 MILLIGRAM, TABLETS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2010	7251247	EXPEDITED (15-DAY)		OT	1000011129	46 YR	Female	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
URINE OUTPUT INCREASED	LEXAPRO	S	ORAL	10 MG, ORAL		
AMNESIA						
DIARRHOEA						
DIZZINESS						
Dry eye						
EAR PAIN						
FATIGUE						
HEADACHE						
HYPERHIDROSIS						
HYPOTENSION						
MENTAL DISORDER						
MYALGIA						
NECK PAIN						
OROPHARYNGEAL PAIN						
SOMNOLENCE						
VISION BLURRED						
WEIGHT DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2010	7296303	NON-EXPEDITED	Y	HO	A0770993A		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LAMICTAL	S	ORAL			GLAXOSMITHKLINE
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Mar-2010	7304457	DIRECT	N	OT		45 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ERECTILE DYSFUNCTION	LEXAPRO	S	ORAL	10 MG DAILY PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Mar-2010	7307454	DIRECT	N	OT		77 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
STARING	LEXAPRO	S		10/MG 1X DAILY IN THE MORNING		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2010	7307039	DIRECT	N			61 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALCOHOLISM	LEXAPRO	S	ORAL	10 MG ONCE DAILY PO		
ABNORMAL BEHAVIOUR						
LOSS OF CONSCIOUSNESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2010	7307603	DIRECT	N	LT		17 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
THINKING ABNORMAL	CYMBALTA	S				
EMOTIONAL DISORDER	LEXAPRO	S				
ABNORMAL BEHAVIOUR						
ABNORMAL DREAMS						
HALLUCINATION, VISUAL						
INSOMNIA						
PSYCHOMOTOR HYPERACTIVITY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2010	7327623	EXPEDITED (15-DAY)	Y	OT	1000012133	19 YR	Male	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HOSTILITY	LEXAPRO	S	ORAL	ORAL		
AGGRESSION						
CONDITION AGGRAVATED						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2010	7207642	EXPEDITED (15-DAY)	N	OT	A0832872A	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LAMICTAL	S	ORAL	200MG Per day		GLAXOSMITHKLINE
VISUAL IMPAIRMENT	LEXAPRO	S	UNKNOWN			
FALL	KEPPRA	S	ORAL			GLAXOSMITHKLINE
ANXIETY						
DRUG INTOLERANCE						
NAUSEA						
PETIT MAL EPILEPSY						
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2010	6944812	EXPEDITED (15-DAY)	N	OT	1000000357	65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD PRESSURE INCREASED	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
SUPRAVENTRICULAR TACHYCARDIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
CARDIAC MURMUR	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
BURNING SENSATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL; 5 MG (5 MG, 1 IN 1 D), ORAL		
URINARY INCONTINENCE	METOPROLOL	C				
ANXIETY						
FAECAL INCONTINENCE						
HOT FLUSH						
HYPERHIDROSIS						
MUSCULAR WEAKNESS						
MYALGIA						
PALPITATIONS						
TINNITUS						
WITHDRAWAL SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2010	7170403	EXPEDITED (15-DAY)	N	OT	1000003105	35 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HOMICIDE	LEXAPRO	S				
ALCOHOL USE	XANAX	C				
AGITATION	ALCOHOL	C				
FEELING ABNORMAL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2010	7306871	EXPEDITED (15-DAY)	Y	OT	US-AMGEN-QUU395312		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	SENSIPAR	S	UNKNOWN			
MENTAL DISORDER	ZOLOFT	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2010	7330161	EXPEDITED (15-DAY)	N	OT	1000011799	21 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S				
CRYING						
MALAISE						
MATERNAL EXPOSURE DURING PREGNANCY						
MENTAL DISORDER						
PREGNANCY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Mar-2010	7314243	DIRECT	N	OT		57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	LEXAPRO	S	ORAL	10 MG ONCE PER DAY PO	6 MTH	FOREST
CONFUSIONAL STATE						
HEADACHE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2010	7043355	EXPEDITED (15-DAY)	N	LT	1000007006	30 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
CONDITION AGGRAVATED	XANAX	S	ORAL	0.75 MG (0.25 MG,3 IN 1 D), ORAL		
GENERAL PHYSICAL HEALTH DETERIORATION						
GUN SHOT WOUND						
HALLUCINATION, AUDITORY						
MENTAL IMPAIRMENT						
SUICIDE ATTEMPT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2010	7318582	DIRECT	N	LT		59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PLATELET COUNT DECREASED	LEXAPRO	S	ORAL	1 10MG DAILY PO		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2010	7350757	NON-EXPEDITED	N		2010SP000842	75 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	SAPHRIS	S				
	LEXAPRO	S		20 MG		
	PLAVIX	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2010	7320192	EXPEDITED (15-DAY)	Y	OT	1000011892	22 YR	Female	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOMANIA	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
EUPHORIC MOOD	REMERON	C				
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Mar-2010	7323393	DIRECT	Y	DE		49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INSOMNIA	LEXAPRO	S		UNKNOWN	2 WEEK	
AGITATION						
COMPLETED SUICIDE						
DRUG PRESCRIBING ERROR						
FEELING OF DESPAIR						
MEDICATION ERROR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Mar-2010	7325584	DIRECT	Y	DS,LT,OT		18 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERSOMNIA	LEXAPRO	S	ORAL	LEXAPRO /1 TAB/10MG Q DAY PO	14 DAY	
DISSOCIATION						
INCORRECT DOSE ADMINISTERED						
INTENTIONAL SELF-INJURY						
LIVER DISORDER						
SUICIDE ATTEMPT						
VOMITING						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Mar-2010	7317320	EXPEDITED (15-DAY)	N	LT,OT	1000011855	29 YR	Female	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
HOMICIDAL IDEATION	LEXAPRO	S	ORAL	20 MG (10 MG, 2 IN 1 D), ORAL, 10 MG (10 MG, 1 IN 1 D), ORAL, 2.5 MG (5 MG, 1 IN 2 D), ORAL		
DRUG INEFFECTIVE	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
HYPERHIDROSIS	LEXAPRO	S	ORAL	2 MG (2 MG, 1 IN 1 D), ORAL		
PANIC ATTACK	LEXAPRO ORAL SOULTION (ESCITALOPRAM OXALATE)	C				
ANXIETY						
DEPRESSION						
DRY MOUTH						
FATIGUE						
HEADACHE						
INSOMNIA						
SELF-INJURIOUS IDEATION						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Mar-2010	7241583	EXPEDITED (15-DAY)	Y	OT	1000010863	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VISUAL IMPAIRMENT	LEXAPRO	S	ORAL	(10 MG), ORAL; (30 MG), ORAL		
FALL	LAMICTAL	S	ORAL	(1 IN 1 D), ORAL; (100 MG), ORAL; (200 MG), ORAL; (475 MG), ORAL; (500 MG), ORAL		
ANXIETY	KEPPRA	S	ORAL	ORAL; (3000 MG), ORAL		
CONVULSION						
NAUSEA						
OVERDOSE						
PETIT MAL EPILEPSY						
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Mar-2010	7330066	DIRECT	N	HO,LT,OT		63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE TIGHTNESS	LEXAPRO	S		10MG 1X DAY		
PALPITATIONS						
SUPRAVENTRICULAR TACHYCARDIA						
TREATMENT FAILURE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Mar-2010	7330469	DIRECT	N	OT		43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE SPASMS	LEXAPRO	S	ORAL	10 MG 1/DAY PO		FOREST
MUSCLE TWITCHING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Mar-2010	7331508	EXPEDITED (15-DAY)	Y	OT	US-BAXTER-2010BH007086	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HAEMOLYTIC ANAEMIA	GAMMAGARD LIQUID	S	INTRAVENOUS			
	GAMMAGARD LIQUID	S	INTRAVENOUS			
	GAMMAGARD LIQUID	S	INTRAVENOUS			
	GAMMAGARD LIQUID	S	INTRAVENOUS			
	LEXAPRO	S	UNKNOWN			
	TYLENOL	C				
	BENADRYL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Mar-2010	7351836	EXPEDITED (15-DAY)	N	OT	1000012584		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	(1 IN 1 D), ORAL		
AMNESIA						
HEADACHE						
MUSCLE SPASMS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Mar-2010	7341832	EXPEDITED (15-DAY)	Y	OT	1000009316	37 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PERSONALITY CHANGE	LEXAPRO	S	ORAL	30 MG (30 MG, 1 IN 1 D), ORAL		
AFFECTIVE DISORDER						
AMNESIA						
EMOTIONAL DISORDER						
FEAR						
HEAD INJURY						
HIGH RISK SEXUAL BEHAVIOUR						
JUDGEMENT IMPAIRED						
OVERDOSE						
ROAD TRAFFIC ACCIDENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Mar-2010	7355318	EXPEDITED (15-DAY)	Y	OT	1000012688		Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	ORAL		
CONDITION AGGRAVATED						
DEPRESSION						
FATIGUE						
LOSS OF LIBIDO						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Mar-2010	7336351	EXPEDITED (15-DAY)	Y	OT	US-WYE-H14189210	74 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CATARACT	PRISTIQ EXTENDED RELEASE	S	ORAL			WYETH
WEIGHT DECREASED	CELEBREX	S	ORAL			
MEDICATION ERROR	LEXAPRO	S	ORAL	unknown		LUNDBECK
EYE LASER SURGERY	SYNTHROID	C	ORAL	125 mcg daily		
VISUAL ACUITY REDUCED	PRILOSEC	C		unknown		MERCK SHARP AND DOHME
	PRILOSEC	C				MERCK SHARP AND DOHME
	FOLIC ACID	C		unknown		UNKNOWN
	ACTONEL	C	ORAL	unknown		PROCTER AND GAMBLE
	GLUCOSE	C		unknown		UNKNOWN
	CALCIUM	C		unknown		UNKNOWN
	VITAMIN B COMPLEX	C		unknown		UNKNOWN
	VITAMIN D	C		unknown		UNKNOWN
	ZOCOR	C	ORAL			MERCK SHARP AND DOHME

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Mar-2010	7344690	DIRECT		DS		58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NERVE INJURY	LEXAPRO	S		1 A DAY		
DIZZINESS						
HYPERHIDROSIS						
MUSCLE TWITCHING						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Mar-2010	7346106	DIRECT	N	HO,OT,RI		49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	1/2 TAB EVERY DAY PO		
PSYCHIATRIC EVALUATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Mar-2010	7357852	EXPEDITED (15-DAY)	Y	OT	1000012689	74 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DISINHIBITION	LEXAPRO	S	ORAL	10 MG, ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Apr-2010	7340985	EXPEDITED (15-DAY)	Y	OT	US-ABBOTT-10P-163-0633967-00	18 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	DIVALPROEX SODIUM	S	ORAL			
AMNESIA	LEXAPRO	S	ORAL			
LOSS OF CONSCIOUSNESS	BUSPIRONE	C	ORAL			
DIZZINESS	ALBUTEROL	C	INHALATION			
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Apr-2010	7303464	EXPEDITED (15-DAY)	Y	HO	1000011742	57 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEPATITIS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL		
	TRADAZOLAM (TABLETS)	C				
	OMEPRAZOLE	C				
	LORMETAZEPAM (TABLETS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Apr-2010	7351082	DIRECT	Y	DS,RI		40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALOPECIA AREATA	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Apr-2010	7356497	EXPEDITED (15-DAY)	Y	DE	1000012705	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TOXICITY TO VARIOUS AGENTS	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
	VISTARIL	S	ORAL	100 MG (50 MG, 2 IN 1 D), ORAL		
	METHADONE HYDROCHLORIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Apr-2010	7349934	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010040671	74 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION	ZOLOFT	S		UNK		PFIZER
ANXIETY	CYMBALTA	S		UNK		
DIVERTICULITIS	LEXAPRO	S		UNK		
ABDOMINAL DISCOMFORT						
ABDOMINAL PAIN UPPER						
ABNORMAL DREAMS						
CONDITION AGGRAVATED						
HYPERTENSION						
INSOMNIA						
MENTAL IMPAIRMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Apr-2010	7352068	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010042037	20 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	CHANTIX	S	ORAL	0.5 mg, 1x/day		PFIZER
DRUG INTERACTION	CHANTIX	S	ORAL	1 mg, 2x/day		PFIZER
DISSOCIATION	SEROQUEL	S	ORAL	300 mg, 1x/day		
	LEXAPRO	S	ORAL	20 mg, 1x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Apr-2010	7357866	DIRECT	Y	DE		54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	OPHTHALMIC	10 MG DAILY OPHTHALMIC	2 WEEK	
INTENTIONAL SELF-INJURY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Apr-2010	7361385	EXPEDITED (15-DAY)	N	OT	1000012956	41 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HOMICIDE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
INSOMNIA	ATIVAN	C				
ENERGY INCREASED						
IMPRISONMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Apr-2010	7375434	NON-EXPEDITED	N		1000010793	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	BYSTOLIC	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
DIARRHOEA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Apr-2010	7309628	EXPEDITED (15-DAY)	Y	OT	1000009096	56 YR	Female	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL; 5 MG (5 MG, 1 IN 1 D), ORAL		
	MEMANTINE HYDROCHLORIDE	S	ORAL	SEE IMAGE		
	MEMANTINE HYDROCHLORIDE	S	ORAL	20 MG (10 MG, 2 IN 1 D), ORAL; 15 MG (7.5 MG, 2 IN 1 D), ORAL; 10 MG (5 MG, 2 IN 1 D), ORAL		
	OSTEOPHOS D3 (SOLUTION)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Apr-2010	7360130	DIRECT				27 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALCOHOL POISONING	LEXAPRO	S	ORAL	20MG ONCE PER DAY PO		
ALCOHOL INTERACTION						
AMNESIA						
LOSS OF CONSCIOUSNESS						
PRODUCT QUALITY ISSUE						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Apr-2010	7362392	DIRECT	Y	OT		55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRURITUS	LEXAPRO	S	ORAL	10 MG PO DAILY		
RASH ERYTHEMATOUS	BENADRYL	S	ORAL	50 MG PO Q6 PRN		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Apr-2010	7362393	DIRECT	Y	OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FIBROMYALGIA	PROZAC	S	ORAL	20 - 60 MG DAILY PO 1990'S - 2008		
CHRONIC FATIGUE SYNDROME	LEXAPRO	S	ORAL	20 MG DAILY PO 2009 (MAR) - 210 (MAR)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Apr-2010	7367794	EXPEDITED (15-DAY)	Y	HO	1000013148	67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TRANSIENT ISCHAEMIC ATTACK	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
	TRAMADOL HYDROCHLORIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Apr-2010	7365601	DIRECT	N	RI		76 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TINNITUS	LEXAPRO	S	ORAL	ONE HALF OF A 10 MG. TABLET EACH DAY PO	7 DAY	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Apr-2010	7366176	DIRECT	Y	OT		30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING HOT	LEXAPRO	S				
RASH ERYTHEMATOUS	PROTONIX	S				
DIZZINESS						
DRY MOUTH						
DRY THROAT						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2010	6096214	EXPEDITED (15-DAY)	Y	HO,LT	S06-NLD-02883-01	75 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC FAILURE CONGESTIVE	LEXAPRO	S	ORAL	20 MG (20 MG, ONCE A DAY), ORAL		
DYSPNOEA	PANTOZOL	C				
ELECTROCARDIOGRAM QT PROLONGED	SALBUTAMOL AER (SALBUTAMOL) (100 MICROGRAM) (SALBUTAMOL)	C				
CARDIAC ARREST	SERETIDE AEROSOL (25 MICROGRAM)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2010	7315644	EXPEDITED (15-DAY)	Y	HO,LT	1000011919		Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC ARREST	LEXAPRO	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2010	7358671	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2010046461	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Toxicity to various agents	VISTARIL	S	ORAL	50 mg, 2x/day		PFIZER
	LEXAPRO	S	ORAL	20 mg, 1x/day		
	LEXAPRO	S				
	METHADONE	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Apr-2010	7369094	DIRECT	N	HO		46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MYOCLONUS	LEXAPRO	S	ORAL	10 MG 1X DAILY PO		
RESTLESS LEGS SYNDROME						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Apr-2010	7307008	NON-EXPEDITED	N		US-JNJFOC-20100300561	15 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	RISPERDAL CONSTA	S	INTRAMUSCULAR			
PSYCHOTIC DISORDER	RISPERDAL CONSTA	S	INTRAMUSCULAR			
DEPRESSION	RISPERDAL CONSTA	S	INTRAMUSCULAR			
MANIA	RISPERDAL CONSTA	S	INTRAMUSCULAR			
GAIT DISTURBANCE	TOPAMAX	S	ORAL			
MIGRAINE	LEXAPRO	S	ORAL			
WRONG TECHNIQUE IN DRUG USAGE PROCESS	PROZAC	S	ORAL			
INJECTION SITE PAIN	VYVANSE	C	ORAL			
IRRITABILITY	RECLIPSEN	C	ORAL			
AGGRESSION						
ANXIETY						
INSOMNIA						
MOOD ALTERED						
RESTLESSNESS						
THERAPEUTIC RESPONSE DECREASED						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Apr-2010	7362777	NON-EXPEDITED	N		US-ASTRAZENECA-2009SE 18009	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR	TOPROL XL	S	ORAL		2 YR	
VASODILATION PROCEDURE	TOPROL XL	S	ORAL			
	LEXAPRO	S	ORAL		2 YR	
	LEXAPRO	S	ORAL		5 DAY	
	LEXAPRO	S	ORAL			
	XANAX	C				
	METFORMIN HYDROCHLORIDE	C				
	PRILOSEC	C				
	EVISTA	C				
	UNITHROID	C				
	VITAMINS NOS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Apr-2010	7362964	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-15015597	11 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OESOPHAGEAL SPASM	ABILIFY	S	ORAL			
	ABILIFY	S	ORAL			
	ABILIFY	S	ORAL			
	LEXAPRO	S				
	SEROQUEL	S				
	DAYTRANA	S		Patch		
	CLONIDINE	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Apr-2010	7360968	EXPEDITED (15-DAY)	Y	HO	1000012816	76 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ENCEPHALOPATHY	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	INSULIN	C				
	LISINOPRIL	C				
	LASIX	C				
	TOPROL XL	C				
	CARDIZEM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Apr-2010	7361315	EXPEDITED (15-DAY)	N	OT	US-RB-001798-10	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
POOR QUALITY SLEEP	SUBOXONE	S	SUBLINGUAL			
DYSKINESIA	LEXAPRO	S	UNKNOWN	Dosing details unknown		
INFLUENZA LIKE ILLNESS	WELLBUTRIN	S	UNKNOWN	Dosing details unknown		
HAND FRACTURE	LUNESTA	S	UNKNOWN	Dosing details unknown		
HALLUCINATION	AMBIEN	S	UNKNOWN	10 mg		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Apr-2010	7371975	DIRECT	N	DS,LT,OT		18 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCULOSKELETAL PAIN	LUPRON DEPOT	S		11.25 MG LUPRON DEPOT 1 (3MO. DOSE)		ABBOTT
BONE DISORDER	LEXAPRO	S				
ACTIVITIES OF DAILY LIVING IMPAIRED						
AMENORRHOEA						
AMNESIA						
ARTHRALGIA						
ARTHROPATHY						
ASTHENIA						
BACK PAIN						
DECREASED APPETITE						
DEPRESSION						
DISTURBANCE IN ATTENTION						
DIZZINESS						
EDUCATIONAL PROBLEM						
HEADACHE						
HYPERAESTHESIA						
HYPOAESTHESIA						
IMPAIRED WORK ABILITY						
NAUSEA						
NECK PAIN						
PHOTOPHOBIA						
SUICIDE ATTEMPT						
THYROID DISORDER						
THYROID NEOPLASM						
UNEVALUABLE EVENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Apr-2010	7376996	EXPEDITED (15-DAY)	Y	OT	1000013211	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PARAESTHESIA	LEXAPRO	S	ORAL	20 MG (10 MG,2 IN 1 D),ORAL		
SUDDEN ONSET OF SLEEP	TOPROL XL	C				
DEAFNESS	LYRICA	C				
VISION BLURRED	VALIUM	C				
EYE MOVEMENT DISORDER	OXYCODONE (TABLETS)	C				
DYSARTHRIA	CELEBREX	C				
ARTHROPOD BITE						
INFECTED BITES						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Apr-2010	7385697	DIRECT	Y				Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEXUAL DYSFUNCTION	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Apr-2010	7376806	DIRECT	Y	OT		58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BRADYCARDIA	LEXAPRO	S	ORAL	10 MG QD PO		FOREST
AFFECT LABILITY						
CHEST INJURY						
COGNITIVE DISORDER						
CONVULSION						
DIZZINESS						
ELECTROCARDIOGRAM ABNORMAL						
ELECTROENCEPHALOGRAM ABNORMAL						
FATIGUE						
FEELING OF BODY TEMPERATURE CHANGE						
GRAND MAL CONVULSION						
HAEMORRHAGE						
HEADACHE						
HEAD INJURY						
LACERATION						
LOSS OF CONSCIOUSNESS						
POST CONCUSSION SYNDROME						
PRESYNCOPE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Apr-2010	7334085	EXPEDITED (15-DAY)	Y	OT	1000012321	27 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGGRESSION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
PHYSICAL ASSAULT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Apr-2010	7372551	NON-EXPEDITED	N		US-ASTRAZENECA-2010SE08150	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BURNING SENSATION	NEXIUM	S	ORAL			ASTRAZENECA
ASTHENOPIA	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-May-2010	7374622	NON-EXPEDITED	N		US-ASTRAZENECA-2009UW05839		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING ABNORMAL	NEXIUM	S	ORAL			ASTRAZENECA
GASTROOESOPHAGEAL REFLUX DISEASE	LEXAPRO	S				
DRUG INEFFECTIVE						
DYSGEUSIA						
INSOMNIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-May-2010	7381519	DIRECT	N	OT,RI		35 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEXUAL DYSFUNCTION	LEXAPRO	S	ORAL	20MG ONCE DAILY PO		FOREST
ANAESTHESIA						
ANORGASMIA						
DIARRHOEA						
DIZZINESS						
EUPHORIC MOOD						
PARAESTHESIA						
UROGENITAL DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-May-2010	7383004	DIRECT	N	HO,LT,OT,RI		86 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	LEXAPRO	S	ORAL	10 MG ONCE DAILY PO		
ABNORMAL BEHAVIOUR						
ABNORMAL WEIGHT GAIN						
ATRIAL FIBRILLATION						
CEREBROVASCULAR ACCIDENT						
DYSARTHRIA						
DYSPNOEA						
FALL						
FEELING ABNORMAL						
FLUID RETENTION						
GAIT DISTURBANCE						
HAEMORRHAGE						
PARAESTHESIA						
TRANSIENT ISCHAEMIC ATTACK						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-May-2010	7319624	EXPEDITED (15-DAY)	Y	OT	1000011973	22 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FOOD ALLERGY	LEXAPRO	S	ORAL	10MG, ORAL; 15 MG, ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-May-2010	7351932	EXPEDITED (15-DAY)	Y	OT	1000012612	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NIGHT BLINDNESS	LEXAPRO	S	ORAL	10 MG (10MG, 1 IN 1D), ORAL, 5MG (5MG, 1 IN1D), ORAL 10MG (10MG 1 IN 1D ORAL) 5 MG (5MG 1 IN1D) ORAL		
CATARACT	FENTANYL CITRATE	C				
OPTIC NEUROPATHY	LORTAB	C				
PHOTOPHOBIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-May-2010	7385628	DIRECT	Y	DS,RI		63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIABETES MELLITUS	RISPERDAL	S	ORAL	RISPERADOL TWICE A DAY ORAL TAB		
Balance disorder	LEXAPRO	S	ORAL	LEXAPRO ONCE A DAY ORAL TAB		FOREST
MUSCULOSKELETAL STIFFNESS	BENZOPROPINE	C				
HEART RATE IRREGULAR	COGENTIN	C				
ASTHENIA						
BLOOD CHOLESTEROL ABNORMAL						
BREAST MASS						
HYPERTENSION						
MUSCULAR WEAKNESS						
OEDEMA PERIPHERAL						
PERIORBITAL OEDEMA						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-May-2010	7386860	EXPEDITED (15-DAY)	N	OT	1000013405	29 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG), ORAL		
EUPHORIC MOOD	DEPAKOTE ER	S				
CONDITION AGGRAVATED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-May-2010	7381231	EXPEDITED (15-DAY)	Y	DS	US-WYE-H14853710	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	PRISTIQ EXTENDED RELEASE	S	ORAL			WYETH
NERVOUSNESS	VALIUM	C		unknown		ROCHE
HEADACHE	LEXAPRO	S	ORAL			LUNDBECK
ENERGY INCREASED	LEXAPRO	S	ORAL			LUNDBECK
IRRITABILITY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-May-2010	7391982	EXPEDITED (15-DAY)	Y	LT	1000013712	63 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HOMICIDE	LEXAPRO	S	ORAL	10 MG, ORAL		
	KEPPRA	S	ORAL	250 MG, ORAL		
	CYRESS CAPSULE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-May-2010	7392912	EXPEDITED (15-DAY)	Y	HO	1000013488		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-May-2010	7385421	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-10P-163-0643069-00	29 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	DEPAKOTE ER	S		Increased to an unknown dose		
EUPHORIC MOOD	LEXAPRO	S	ORAL			
CONDITION AGGRAVATED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-May-2010	7386677	NON-EXPEDITED	N		A0850509A		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	TREXIMET	S	ORAL		1 DAY	GLAXOSMITHKLINE
VOMITING	LEXAPRO	S	UNKNOWN		5 YR	
CHEST DISCOMFORT						
CHEST PAIN						
DRUG INTERACTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-May-2010	7395478	EXPEDITED (15-DAY)	Y	HO	1000013726	97 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Spinal fracture	LEXAPRO	S	ORAL	5 MG, ORAL		
ATRIAL FIBRILLATION	LONG ACTING TOLTERODINE TARTRATE	C				
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	ATENOLOL	C				
FALL	FUROSEMIDE	C				
URINARY TRACT INFECTION	LISINOPRIL	C				
BLOOD PRESSURE INCREASED	LORAZEPAM	C				
BLOOD POTASSIUM DECREASED	DOCUSATE	C				
BLOOD MAGNESIUM DECREASED	CIPROFLOXACIN	C				
	METHYLCELLULOSE	C				
	MULTI-VITAMIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-May-2010	7397017	EXPEDITED (15-DAY)	Y	OT	1000013818	81 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BILE DUCT OBSTRUCTION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL		
YELLOW SKIN						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-May-2010	7397018	DIRECT	Y	DS		27 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF LIBIDO	LEXAPRO	S	ORAL	10 MG 1/DAY P/O		
ERECTILE DYSFUNCTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-May-2010	7398668	EXPEDITED (15-DAY)	Y	HO	1000013789	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
CEREBROVASCULAR ACCIDENT	PLAVIX	S	ORAL	75 MG (75 MG, 1 IN 1 D), ORAL		
	LASIX (40 MILLIGRAM, TABLETS)	C				
	GLUCOPHAGE XR (500 MILLIGRAM, TABLETS)	C				
	POTASSIUM	C				
	TOPROL XL	C				
	PROVENTIL (INHALANT)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-May-2010	7407483	EXPEDITED (15-DAY)	Y	OT	1000013732	19 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RETINAL INJURY	LEXAPRO	S	ORAL	10 MG (10MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-May-2010	7376555	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2010039102		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MEMORY IMPAIRMENT	ARTHROTEC	S		UNK		PFIZER
VISION BLURRED	LYRICA	S	ORAL	25 mg, 1x/day		PFIZER
DIZZINESS	LYRICA	S				PFIZER
ANXIETY	LYRICA	S				PFIZER
HOT FLUSH	NEURONTIN	S		UNK		PFIZER
NAUSEA	LEXAPRO	S		UNK		
ABDOMINAL DISCOMFORT	ESTRACE	C		UNK		
HAEMOGLOBIN INCREASED	FEXOFENADINE	C		UNK		
HAEMATOCRIT INCREASED	AVAPRO	C		300 mg, UNK		
	AVAPRO	C				
	SYNTHROID	C		0.1 mg, 1x/day		
	SYNTHROID	C				
	MORPHINE SULFATE	C		UNK		
	MS CONTIN	C		15 mg, 2x/day		
	ESTRADIOL	C		1 mg, 1x/day		
	ALLEGRA	C		180 mg, as needed		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-May-2010	7396727	EXPEDITED (15-DAY)	N	OT	NL-ASTRAZENECA-2010SE 22555		Female	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
THINKING ABNORMAL	SEROQUEL XR	S	ORAL			ASTRAZENECA
DEPRESSION	CITALOPRAM	S	UNKNOWN			
DENTAL CARIES	LEXAPRO	S	UNKNOWN			
WEIGHT INCREASED	NORTRIPTYLINE HYDROCHLORIDE	S	UNKNOWN			
DRY MOUTH	PAROXETINE HYDROCHLORIDE	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2010	5807234	EXPEDITED (15-DAY)	Y	OT	S05-USA-01283-01	27 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2010	7406602	DIRECT					Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S	ORAL	10 MG DAILY P.O.		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2010	7406603	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S	ORAL	20MG DAILY PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2010	7406604	DIRECT	Y				Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S	ORAL	20 MG DAILY P.O.		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-May-2010	7399042	EXPEDITED (15-DAY)	N	OT	US-WATSON-2010-06562		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSED LEVEL OF CONSCIOUSNESS	HYDROXYCHLOROQUINE SULFATE	S	ORAL	200 mg, daily	91 DAY	WATSON
SYNCOPE	LEXAPRO	S	ORAL	10 mg, daily	3 DAY	
TREMOR	LEXAPRO	S				
ASTHENIA	MOBIC	C	ORAL	UNK		
FALL	XOPENEX	C	INHALATION	UNK		
AGGRESSION						
APHASIA						
BLEPHAROSPASM						
BLOOD KETONE BODY						
DECREASED APPETITE						
DEHYDRATION						
DEPRESSED MOOD						
DIZZINESS						
DRUG INTERACTION						
FEELING ABNORMAL						
HEADACHE						
HEART RATE IRREGULAR						
HYPOKALAEMIA						
MENTAL DISORDER						
MOOD ALTERED						
MUSCLE SPASMS						
MUSCLE TWITCHING						
MYALGIA						
NAUSEA						
PARAESTHESIA						
PERSONALITY CHANGE						
WHITE BLOOD CELL COUNT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-May-2010	7406623	DIRECT	Y	OT		55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VISION BLURRED	LEXAPRO	S	ORAL	10 MD QD PO		FOREST
Dry eye						
RETINAL TEAR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-May-2010	7407946	EXPEDITED (15-DAY)	Y	OT	1000013988	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Spinal fracture	LEXAPRO	S		20 MG (20 MG, 1 IN 1 D)		
Meniscus injury	CELEBREX	S		(3 IN 1 D)		
NAUSEA	SEROQUEL	S		600 MG (600 MG, AT BEDTIME)		
ABDOMINAL PAIN UPPER	TEGRETOL	C				
DRUG INEFFECTIVE	LOPRESSOR	C				
POOR QUALITY SLEEP	GLUCOPHAGE	C				
	PRILOSEC	C				
	DICHLORALPHENAZONE/ ISOMETHEPTENE MUCATE/ ACETAMINOPHEN	C				
	SYNTHROID	C				
	KLONOPIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-May-2010	7407947	EXPEDITED (15-DAY)	Y	HO	1000013969	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MENTAL STATUS CHANGES	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL; 20 MG (200 MG, 1 IN 1 D), ORAL		
	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL; 5 MG (5 MG, 1 IN 1 D), ORAL		
	TACROLIMUS	S	ORAL	ORAL		
	ACYCLOVIR	C				
	FLUDROCORTISONE	C				
	TRIMETHOPRIM	C				
	MAGNESIUM	C				
	LASIX	C				
	METOPROLOL	C				
	OMEPRAZOLE	C				
	NYSTATIN	C				
	MULTIVITAMINS	C				
	ASPIRIN	C				
	OXYCODONE	C				
	CYCLOBENZAPRINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-May-2010	7410435	DIRECT	N	DS			Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSKINESIA	RISPERDAL	S		1 TABLET ONCE BEDTIME		
IMPAIRED WORK ABILITY	LEXAPRO	S		1 TABLET ONCE MORNING		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2010	7405693	EXPEDITED (15-DAY)	N	OT	US-ASTRAZENECA-2010SE23095	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Thoracic vertebral fracture	SEROQUEL	S	ORAL			ZENECA
Meniscus injury	CELEBREX	S	ORAL			
THYROID DISORDER	EFFEXOR	S	ORAL		0 YR	
ANXIETY	LEXAPRO	S	UNKNOWN			
PANIC ATTACK	CYMBALTA	S	ORAL		0 MTH	
NAUSEA	NEURONTIN	C				
ABDOMINAL PAIN UPPER	GLUCOPHAGE	C				
INSOMNIA	PRILOSEC	C				
DRUG INEFFECTIVE	DICHLORALPHENAZONE \ISOMETHEPTENE MUCATE	C				
	LORCET	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2010	7405738	EXPEDITED (15-DAY)	N	OT	A0860846A	74 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION	LAMICTAL	S	ORAL	175MG Twice per day		GLAXOSMITHKLINE
SUICIDAL IDEATION	LEXAPRO	S				
ANGER	DIGOXIN	C				GLAXOSMITHKLINE
CONFUSIONAL STATE	COUMADIN	C				GLAXOSMITHKLINE
	VIMPAT	C				GLAXOSMITHKLINE
	SEROQUEL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2010	7412480	DIRECT	N	RI		62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE CONTRACTIONS INVOLUNTARY	LEXAPRO	S	ORAL	1 1/2 TABLETS DAILY PO		
DRY MOUTH						
LIP DRY						
SALIVARY HYPERSECRETION						
SENSATION OF PRESSURE						
SPEECH DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2010	7413099	EXPEDITED (15-DAY)	Y	OT	1000014040	35 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
TREATMENT NONCOMPLIANCE	XANAX	S	ORAL	0.5 MG, PRN, ORAL		
INAPPROPRIATE SCHEDULE OF DRUG ADMINISTRATION	ATIVAN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jun-2010	7413407	DIRECT					Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S	ORAL	10MG DAILY P.O.		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jun-2010	7413475	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S	ORAL	20MG DAILY PO		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jun-2010	7413484	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S	ORAL	20MG DAILY P.O.		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Jun-2010	7399722	EXPEDITED (15-DAY)	Y	OT	1000013845	29 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D),ORAL		
HYPERREFLEXIA						
NERVOUS SYSTEM DISORDER						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Jun-2010	7418428	EXPEDITED (15-DAY)	Y	OT	1000014234	30 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INTENTIONAL SELF-INJURY	CITALOPRAM HYDROBROMIDE	S	ORAL	20 MG (20 MG, 1 IN 1 D),ORAL		
ANXIETY	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL ; 15 MG (15 MG, 1 IN 1 D),ORAL		
CRYING	HYDROXIZINE (TABLETS)	C				
IMPULSIVE BEHAVIOUR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jun-2010	7418536	DIRECT	Y	DE		44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	20 MG DAILY PO		
IMPAIRED WORK ABILITY	XANAX	S	ORAL	DECREASED FROM 4MG T0 .5 MG DAILY PO		
AKATHISIA						
INSOMNIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jun-2010	7416706	EXPEDITED (15-DAY)	N	OT	1000014124	48 YR	Female	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL		
RESTLESSNESS	REMERON	C				
DIZZINESS	FOSTER	C				
CRYING						
DEPRESSION						
FEELING ABNORMAL						
HYPERHIDROSIS						
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jun-2010	7419521	DIRECT	N	HO,LT,OT,RI		86 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RECTAL HAEMORRHAGE	LEXAPRO	S	ORAL	5 MG 2 X DAILY PO		FOREST
PRODUCT QUALITY ISSUE	LEXAPRO	S				
TRANSFUSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jun-2010	7415524	EXPEDITED (15-DAY)	N	OT	NL-ASTRAZENECA-2010SE22548		Male	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	SEROQUEL	S	ORAL			ZENECA
HOMICIDAL IDEATION	AMITRIPTYLINE HYDROCHLORIDE	S				
WEIGHT INCREASED	LEXAPRO	S				
LIBIDO DECREASED	TRAZODONE HYDROCHLORIDE	S				
APATHY	PROTHIADEN	S				
TOOTH DISORDER	OXAZEPAM	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jun-2010	7415950	NON-EXPEDITED	N		US-ROXANE LABORATORIES, INC.-2010-RO-00694RO	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INCREASED APPETITE	LITHIUM CARBONATE	S	ORAL	600 mg		ROXANE
WEIGHT INCREASED	LITHIUM CARBONATE	S		750 mg		ROXANE
DYSPNOEA	LEXAPRO	S	ORAL	20 mg		
HYPOMANIA	LEXAPRO	S	ORAL	10 mg		
	LEXAPRO	S	ORAL	5 mg		
	TEGRETOL	C	ORAL	600 mg		
	ATIVAN	C	ORAL	1.5 mg		
	VITAMIN D	C				
	HALDOL	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jun-2010	7423926	EXPEDITED (15-DAY)	Y	OT	1000014375	65 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MOVEMENT DISORDER	LEXAPRO	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jun-2010	7427249	EXPEDITED (15-DAY)	Y	HO	2010US001864	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	PROGRAF	S	ORAL	ORAL		
MENTAL STATUS CHANGES	LEXAPRO	S	ORAL	10 MG, UID/QD, ORAL; 5 MG, UID/QD, ORAL; 20 MG, UID/QD, ORAL		
	ACYCLOVIR	C				
	FLUDROCORTISONE ACETATE	C				
	OMEPRAZOLE	C				
	NYSTATIN	C				
	MULTI-VITAMIN	C				
	ASPIRIN (ACETYLSALICYLIC ACID)	C				
	OXYCODONE (OXYCODONE)	C				
	CYCLOBENZAPRINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jun-2010	7419044	EXPEDITED (15-DAY)	N	OT	NL-ASTRAZENECA-2010SE22612		Male	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	SEROQUEL	S	ORAL			ZENECA
HOMICIDAL IDEATION	SEROQUEL	S	ORAL			ZENECA
HEADACHE	CITALOPRAM	S				
NAUSEA	LEXAPRO	S				
INSOMNIA	EFFEXOR	S				
IRRITABILITY	REMERON	C				
LIBIDO DECREASED						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jun-2010	5833301	EXPEDITED (15-DAY)	N	DE,OT	HQWYE547320JUN05	53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	EFFEXOR	S				WYETH
RESTLESSNESS	EFFEXOR	S				WYETH
TREMOR	LEXAPRO	S				
ANXIETY						
CONDITION AGGRAVATED						
DRUG INEFFECTIVE						
GLYCOSYLATED HAEMOGLOBIN INCREASED						
GUN SHOT WOUND						
HYPOGLYCAEMIA						
IMPAIRED WORK ABILITY						
INSOMNIA						
MENTAL IMPAIRMENT						
NERVOUSNESS						
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jun-2010	7420844	EXPEDITED (15-DAY)	N	OT	NL-ASTRAZENECA-2010SE22837		Female	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	SEROQUEL	S	ORAL			ZENECA
HOMICIDAL IDEATION	PROZAC	S				
HEADACHE	LEXAPRO	S				
NAUSEA	AMITRIPTYLINE HYDROCHLORIDE	S				
AGGRESSION						
INSOMNIA						
IRRITABILITY						
LIBIDO DECREASED						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jun-2010	7427780	DIRECT	N	OT		43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRURITUS	LEXAPRO	S	ORAL	10MG ONCE A DAY PO , APPPROX 6-8 MONTHS	6 MTH	FOREST
URTICARIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jun-2010	7431749	EXPEDITED (15-DAY)	Y	HO	1000014447		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
UNEVALUABLE EVENT	LEXAPRO	S				
	ESCITALOPRAM OXALATE	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jun-2010	7435734	DIRECT	N	DE			Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S				FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jun-2010	7436289	DIRECT	N	HO,RI		20 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	LEXAPRO	S	ORAL	20 MG TWICE/ DAY PO		
BIPOLAR DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2010	7427945	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-15155708	28 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PSYCHOTIC DISORDER	ABILIFY	S		Pills		
DEPRESSION	LEXAPRO	S				
DRUG DOSE OMISSION						
EMOTIONAL DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jun-2010	7430691	NON-EXPEDITED	Y	HO	US-PFIZER INC-2008015742	39 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	GEODON	S	ORAL	Q HS		PFIZER
	LEXAPRO	S				
	KLONOPIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jun-2010	7430881	NON-EXPEDITED	Y		US-PFIZER INC-2008028856		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	DEPO-PROVERA	S				PFIZER
METRORRHAGIA	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jun-2010	7451649	EXPEDITED (15-DAY)	N	HO	1000014566	78 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ASTHENIA	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
LETHARGY	GEODON	C				
DIZZINESS	SIMVASTATIN	C				
LOSS OF CONSCIOUSNESS	TRILIPIX	C				
LACERATION	REMERON	C				
BLOOD PRESSURE DIASTOLIC DECREASED	CLONAZEPAM	C				
	AZOR	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2010	7443773	NON-EXPEDITED	Y		US-PFIZER INC-2007036940		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG LEVEL DECREASED	GEODON	S				PFIZER
	LEXAPRO	S				
	ALL OTHER THERAPEUTIC PRODUCTS	C				
	AVODART	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2010	7444399	NON-EXPEDITED	N	OT	US-PFIZER INC-2007090114	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE TWITCHING	GEODON	S	ORAL			PFIZER
BURNING SENSATION	LEXAPRO	S	ORAL	DAILY		
PRURITUS	XANAX	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2010	7444692	NON-EXPEDITED	Y	OT	US-PFIZER INC-2007091513	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LACUNAR INFARCTION	GEODON	S				PFIZER
	GEODON	S				PFIZER
	LEXAPRO	S				
	CELEBREX	C				
	SYNTHROID	C				
	ASA	C				
	LYRICA	C				
	OXYCONTIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2010	7444703	NON-EXPEDITED	Y		US-PFIZER INC-2007083863	13 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ELECTROCARDIOGRAM QT PROLONGED	GEODON	S				PFIZER
TIC	PALIPERIDONE	S				
ANXIETY	LEXAPRO	S	ORAL			
PANIC REACTION	TRAZODONE HYDROCHLORIDE	C				
SINUS ARRHYTHMIA						
WOLFF-PARKINSON-WHITE SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2010	7450075	DIRECT	Y			36 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COUGH	LISINOPRIL AND HYDROCHLOROTHIAZIDE	S	ORAL	1 TAB DAILY PO		LUPIN
	LEXAPRO	S	ORAL	1 TAB DAILY PO		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2010	7455560	EXPEDITED (15-DAY)	N	HO	1000014698	56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
LACERATION	ATIVAN	C				
	AMLODIPINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7445082	NON-EXPEDITED	N		US-PFIZER INC-2007079588	45 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PAIN	XANAX	S				PFIZER
ASTHENIA	ZOLPIDEM TARTRATE	C				
FATIGUE	KLONOPIN	C				
NAUSEA	HYOSCYAMINE SULFATE	C				
DRUG INEFFECTIVE	HYOSCYAMINE SULFATE	C				
AKATHISIA	ULTRAM	C				
DRUG TOLERANCE	XANAX	S				PFIZER
INCORRECT DOSE ADMINISTERED	LEXAPRO	S				
DRUG INTERACTION	LEXAPRO	S				
	VALIUM	S		FREQUENCY: PRN		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7445512	NON-EXPEDITED	Y	LT,OT	US-PFIZER INC-2008026143	83 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR TACHYCARDIA	TIKOSYN	S		EVERY DAY		PFIZER
DRUG INTERACTION	ATENOLOL	C				
	ACETYLSALICYLIC ACID	C				
	LASIX	C				
	SPIRONOLACTONE	C				
	GLUCOSAMINE	C				
	LEXAPRO	S				
	BARIUM	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7445958	NON-EXPEDITED	Y	OT	US-PFIZER INC-2008052204	70 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	ZYVOX	S				PFIZER
PYREXIA	LEXAPRO	S				
MENTAL STATUS CHANGES						
MUSCLE RIGIDITY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7446456	NON-EXPEDITED			US-PFIZER INC-2008088248	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	XANAX	S				PFIZER
FATIGUE	PREVACID	C				
HYPERHIDROSIS	ZETIA	C				
	LEXAPRO	S	ORAL			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7446509	NON-EXPEDITED	Y		US-PFIZER INC-2008085946	46 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
URINARY TRACT INFECTION	XANAX	S				PFIZER
RHINORRHOEA	UROXATRAL	C		UNK		
APATHY	BENTYL	C		UNK		
DRUG INTERACTION	BENTYL	C				
RESTLESSNESS	LIBRAX	C				
IMPATIENCE	LIBRAX	C				
HYPOAESTHESIA	HYOSCYAMINE SULFATE	C		UNK		
CONSTIPATION	HYOSCYAMINE SULFATE	C				
INCREASED APPETITE	MESALAZINE	C		UNK		
WEIGHT INCREASED	MESALAZINE	C				
DIARRHOEA	ULTRAM	C		UNK		
DEPRESSION	AMBIEN	C		UNK		
SEXUAL DYSFUNCTION	ALPRAZOLAM	C		UNK		
ANXIETY	LEXAPRO	S	ORAL	2.5 mg, 1x/day		
AGITATION	LEXAPRO	S	ORAL	1.5 mg, 1x/day		
INSOMNIA	LEXAPRO	S	ORAL	2 mg, 1x/day		
FATIGUE	LEXAPRO	S	ORAL	3 mg, 1x/day		
IRRITABILITY	LEXAPRO	S	ORAL	3.5 mg, 1x/day		
	LEXAPRO	S	ORAL	4 mg, 1x/day		
	LEXAPRO	S	ORAL	4.5 mg, 1x/day		
	LEXAPRO	S	ORAL	5 mg, 1x/day		
	VALIUM	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7446543	NON-EXPEDITED	N		US-PFIZER INC-2008088016		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	XANAX	S				PFIZER
SOMNOLENCE	XANAX XR	S				PFIZER
PANIC ATTACK	PROLIXIN	S				
	IMIPRAMINE	S				
	LEXAPRO	S				
	ELAVIL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7446617	NON-EXPEDITED	N		US-PFIZER INC-2008092147		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VISION BLURRED	XANAX	S				PFIZER
MYDRIASIS	LEXAPRO	S				
OCULAR HYPERAEMIA	EFFEXOR	S				
Dry eye						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7446642	NON-EXPEDITED	N		US-PFIZER INC-2009154057	78 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INSOMNIA	XANAX	S		0.25mg 1/2 tablet at 2:30pm and 1 tablet at 10pm		PFIZER
	ALPRAZOLAM	S				PFIZER
	LEXAPRO	S				
	LUMIGAN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7446731	NON-EXPEDITED	N		US-PFIZER INC-2008156744		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VISUAL IMPAIRMENT	ZYVOX	S		UNK		PFIZER
DRUG INTERACTION	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7446805	NON-EXPEDITED	N		US-PFIZER INC-2008157256	80 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	PROCRIT	S		UNK		
VISION BLURRED	FOSAMAX	C		UNK		
DIPLOPIA	ZOCOR	C		UNK		
VISUAL ACUITY REDUCED	LEVAQUIN	C		UNK		
	RESTORIL	C		UNK		
	VALTREX	C		UNK		
	LASIX	C		UNK		
	POTASSIUM	C		UNK		
	AMARYL	C		UNK		
	TRICOR	C		UNK		
	MUCINEX	C		UNK		
	ZYVOX	S	ORAL	600 mg, 2x/day	3 DAY	PFIZER
	LEXAPRO	S		20 mg, 1x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7446892	NON-EXPEDITED	N		US-PFIZER INC-2009177597	65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ERYTHEMA	XANAX	S	ORAL	UNK		PFIZER
SOMNOLENCE	LEXAPRO	S	ORAL	5 mg, 1x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7447371	NON-EXPEDITED	N		US-PFIZER INC-2009224169	56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	XANAX	S		1 CAPLET 2-3 TIMES A DAY		PFIZER
NIGHT SWEATS	DIPHENHYDRAMINE HYDROCHLORIDE	S	ORAL	50 mg, 1x/day		
	LEXAPRO	S		10 mg, 1x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7447442	NON-EXPEDITED	N		US-PFIZER INC-2009225427	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	XANAX	S	ORAL	UNK		PFIZER
DISTURBANCE IN ATTENTION	LEXAPRO	S	ORAL	10 mg, 1x/day		
	OMEPRAZOLE	C		UNK		
	CLARITIN	C		UNK		
	ADVIL	C		UNK		
	DIPHENHYDRAMINE	C		UNK		
	VITAMINS NOS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7509541	NON-EXPEDITED	Y	OT	US-WYE-H14644910		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	PRISTIQ EXTENDED RELEASE	S		50 MG 1X PER 1 DAY		
BLOOD PRESSURE INCREASED	LEXAPRO	S		UNSPECIFIED DOSE INCREASED		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2010	7529715	NON-EXPEDITED	Y		US-WYE-H14057310		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF LIBIDO	PRISTIQ EXTENDED RELEASE	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jun-2010	7472295	EXPEDITED (15-DAY)	Y	OT	1000014707	18 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
FEELING COLD						
PARALYSIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jul-2010	7457618	DIRECT	N	OT		48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MIGRAINE	LEXAPRO	S				FOREST
ECONOMIC PROBLEM						
IMPULSIVE BEHAVIOUR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jul-2010	7475923	EXPEDITED (15-DAY)	Y	OT	1000014740	90 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION	LEXAPRO	S				
CONVULSION	MULTIPLE SSRI'S (NOS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jul-2010	7326996	EXPEDITED (15-DAY)	Y	OT	IE-ROCHE-629222		Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLICATION OF PREGNANCY	TRASTUZUMAB	S	INTRAVENOUS	LOADING DOSE. FREQUENCY: ONE TIME PER ODOS. ACTUAL DOSE: 732 MG.		ROCHE
	TRASTUZUMAB	S	INTRAVENOUS	MAINTENANCE DOSE, ACTUAL DOSE GIVEN 549 MG ON 03 JAN, 25 JAN, 13 FEB, 3 MAR AND 24 MAR 2006.		ROCHE
	LEXAPRO	S	ORAL			
	LEVOTHYROXINE	S	ORAL			
	DOXORUBICIN	C				
	CYCLOPHOSPHAMIDE	C				
	DOCETAXEL	C		TAKEN ONCE.		
	CITALOPRAM	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jul-2010	7389111	EXPEDITED (15-DAY)	Y	OT	1000013450	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GRAND MAL CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ANXIETY DISORDER	CLONAZEPAM	C				
FALL						
REFUSAL OF TREATMENT BY PATIENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jul-2010	7455686	EXPEDITED (15-DAY)	Y	DE,OT	US-PFIZER INC-2010079804		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	GEODON	S	ORAL	40 mg, 2x/day		PFIZER
DRUG INEFFECTIVE	LEXAPRO	S		UNK		
SELF-MEDICATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jul-2010	7456861	NON-EXPEDITED	N		US-PFIZER INC-2007071087	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE SPASMS	ZOLOFT	S				PFIZER
	LEXAPRO	S				
	PANCRELIPASE	C				
	REGLAN	C				
	ERYTHROMYCIN	C				
	VITAMINS	C				
	CALCIUM	C				
	AMBIEN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2010	6255636	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2007014646	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LYRICA	S		50 mg, 3x/day		PFIZER
BLADDER DISORDER	LEXAPRO	S		UNK		
ABDOMINAL DISTENSION						
ABDOMINAL PAIN						
VISUAL IMPAIRMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2010	7459403	NON-EXPEDITED	N		US-PFIZER INC-2006117679	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	CHANTIX	S				PFIZER
DIARRHOEA	LEXAPRO	S				
	VYTORIN	C				
	ZOCOR	C				
	LOPRESSOR	C				
	COZAAR	C				
	ISOSORBIDE	C				
	PLETAL	C				
	FISH OIL	C				
	VITAMIN E	C				
	ACETYLSALICYLIC ACID	C				
	VITAMIN C	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2010	7459443	NON-EXPEDITED	N	OT	US-PFIZER INC-2006118392	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CRYING	CHANTIX	S	ORAL			PFIZER
DEPRESSION	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2010	7460110	NON-EXPEDITED	N		US-PFIZER INC-2006140548	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABNORMAL DREAMS	CHANTIX	S				PFIZER
NAUSEA	LEXAPRO	S				
TOBACCO WITHDRAWAL SYMPTOMS	LORATADINE	C				
	ZOCOR	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2010	7460154	NON-EXPEDITED	N		US-PFIZER INC-2006142998	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING ABNORMAL	CHANTIX	S				PFIZER
AGITATION	LEXAPRO	S				
DISTURBANCE IN ATTENTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2010	7461053	NON-EXPEDITED	Y		US-PFIZER INC-2006140251	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SOMNOLENCE	CHANTIX	S	ORAL			PFIZER
DRUG INTERACTION	VERAPAMIL HYDROCHLORIDE	C				
DYSGEUSIA	BENICAR	C				
HOT FLUSH	DDAVP	C				
PARAESTHESIA	MONTELUKAST SODIUM	C				
FATIGUE	ALLEGRA	C				
	FAMOTIDINE	C				
	PREMARIN	C				
	POTASSIUM	C				
	THEOPHYLLINE	C				
	TIOTROPIUM BROMIDE	C	INHALATION			
	CHANTIX	S				PFIZER
	LAMICTAL	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2010	7466196	DIRECT	N	OT		45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	5MG EVERYDAY PO		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2010	7492641	EXPEDITED (15-DAY)	N	DS	DSA_43435_2010		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FIBROMYALGIA	WELLBUTRIN XL	S	ORAL	(100 MG QD ORAL), (150 MG QD ORAL)		
CONFUSIONAL STATE	LEXAPRO	S		(DF)		
WEIGHT INCREASED	PERCOCET	C				
FALL	KLONOPIN	C				
UNEVALUABLE EVENT	TRAZODONE HYDROCHLORIDE	C				
IMPAIRED WORK ABILITY						
LOSS OF EMPLOYMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2010	6268075	NON-EXPEDITED	Y	OT	US-PFIZER INC-2007010630	32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEART RATE INCREASED	CHANTIX	S				PFIZER
HYPOTENSION	LEXAPRO	S				
BODY TEMPERATURE DECREASED						
DIZZINESS						
DRUG INTERACTION						
FEELING HOT						
HYPERHIDROSIS						
NAUSEA						
SEROTONIN SYNDROME						
STRESS						
VOMITING						

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2010	7417995	EXPEDITED (15-DAY)	N	OT	US-SHIRE-SPV1-2010-01039		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INTENTIONAL OVERDOSE	VYVANSE	S	ORAL	20 - 70 mg capsules, One dose	1 DAY	
INSOMNIA	VYVANSE	S		70 mg, 1x/day:qd in AM	332 DAY	
VOMITING	LEXAPRO	S		20mg daily	2 DAY	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2010	7463150	NON-EXPEDITED	N		US-PFIZER INC-2007010045	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NERVOUSNESS	CHANTIX	S				PFIZER
WITHDRAWAL SYNDROME	LEXAPRO	S				
HEADACHE	WELLBUTRIN	C				
ABNORMAL DREAMS	LIPITOR	C				
ANGER	AMBIEN	C				
ANXIETY	ZELNORM	C				
STRESS	XANAX	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2010	7464244	NON-EXPEDITED	N		US-PFIZER INC-2007020032	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABNORMAL DREAMS	CHANTIX	S				PFIZER
SLEEP DISORDER	METFORMIN HYDROCHLORIDE	C				
DRUG INTERACTION	CRESTOR	C				
	ACETYLSALICYLIC ACID	C				
	SAW PALMETTO	C				
	OMEGA-3 TRIGLYCERIDES	C				
	ADVIL	C				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2010	7464284	NON-EXPEDITED	Y		US-PFIZER INC-2007010277	21 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD PRESSURE INCREASED	CHANTIX	S				PFIZER
	LEXAPRO	S				
	LEXAPRO	S				
	ADVAIR DISKUS	C	INHALATION			
	ALBUTEROL	C	INHALATION			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jul-2010	7467742	NON-EXPEDITED	N		US-PFIZER INC-2007028656	31 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	VARENICLINE TARTRATE	S				PFIZER
SOMNOLENCE	NEURONTIN	S				PFIZER
NAUSEA	LEXAPRO	S				
ABDOMINAL PAIN						
ABNORMAL DREAMS						
HEADACHE						
MIDDLE INSOMNIA						
NIGHTMARE						
VOMITING						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jul-2010	7468255	NON-EXPEDITED	N	OT	US-PFIZER INC-2007030841	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MENTAL IMPAIRMENT	CHANTIX	S				PFIZER
DEPRESSION	LEXAPRO	S				
CRYING						
DIZZINESS						
LETHARGY						
NAUSEA						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2010	7470318	NON-EXPEDITED	N		US-PFIZER INC-2007037583	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	CHANTIX	S				PFIZER
	LEXAPRO	S				
	LOTREL	C				
	TOPROL XL	C				
	GEMFIBROZIL	C				
	ZOCOR	C				
	ASPIRINE	C				
	LUNESTA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2010	7471000	NON-EXPEDITED	N		US-PFIZER INC-2007041984		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LETHARGY	CHANTIX	S				PFIZER
ABNORMAL DREAMS	LEXAPRO	S				
	PREVACID	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2010	7471573	NON-EXPEDITED	N		US-PFIZER INC-2007035298	50 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSGEUSIA	CHANTIX	S				PFIZER
FLATULENCE	LEXAPRO	S				
ERECTILE DYSFUNCTION						
HYPOAESTHESIA						
NERVOUS SYSTEM DISORDER						
PARAESTHESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2010	7471756	NON-EXPEDITED	N		US-PFIZER INC-2007049673	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VOMITING	CHANTIX	S				PFIZER
EMOTIONAL DISORDER	LEXAPRO	S				
CRYING						
ILL-DEFINED DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2010	7472108	NON-EXPEDITED	Y		US-PFIZER INC-2007042410	47 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MALAISE	CHANTIX	S				PFIZER
DIZZINESS	ACETYLSALICYLIC ACID	C				
NAUSEA	ALEVE	C				
IRRITABILITY	OPIOIDS	C				
EMOTIONAL DISORDER	LEXAPRO	S				
DRUG INTERACTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2010	7498495	EXPEDITED (15-DAY)	N	OT	1000014694	31 YR	Male	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANXIETY	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
CONDITION AGGRAVATED	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
VERTIGO	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DRUG INEFFECTIVE	VALERIAN OFFICINALIS	C				
	CLONAZEPAM	C				
	ZOLPIDEM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jul-2010	7391179	EXPEDITED (15-DAY)	N	DE	US-SHIRE-SPV1-2010-00928		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	VYVANSE	S	UNKNOWN	30 mg, 1x/day:qd		
VENTRICULAR ARRHYTHMIA	HEROIN	S				
	LAMICTAL	S	UNKNOWN	200 mg, 1x/day:qd		
	ABILIFY	S	UNKNOWN	30 mg, 1x/day:qd		
	LEXAPRO	S	UNKNOWN	10 mg, 1x/day:qd		
	CLONAZEPAM	S				
	METHADONE HYDROCHLORIDE	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jul-2010	7474089	NON-EXPEDITED	N		US-PFIZER INC-2007055083	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	CHANTIX	S				PFIZER
ANXIETY	LEXAPRO	S				
DRUG INTERACTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jul-2010	7474353	NON-EXPEDITED	Y		US-PFIZER INC-2007058026	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEADACHE	CHANTIX	S				PFIZER
DRUG INEFFECTIVE	PERCOCET	C				
DRUG INTERACTION	METHADONE HYDROCHLORIDE	C				
	VERAPAMIL HYDROCHLORIDE	C				
	HYDROCHLOROTHIAZIDE	C				
	ZOCOR	C				
	TRANXENE T-TAB	C				
	GLUCOPHAGE	C				
	LEXAPRO	S				
	PROVIGIL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jul-2010	7474748	NON-EXPEDITED	Y		US-PFIZER INC-2007061388		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC DISORDER	CHANTIX	S				PFIZER
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jul-2010	7480093	NON-EXPEDITED	N	OT	US-PFIZER INC-2007080688	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PALPITATIONS	CHANTIX	S				PFIZER
FEELING JITTERY	LEXAPRO	S				
NERVOUSNESS	ANTIHYPERTENSIVES	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jul-2010	7480432	NON-EXPEDITED	N	HO	US-PFIZER INC-2007080965		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MIGRAINE	CHANTIX	S				PFIZER
HEADACHE	SEROQUEL	S				
CRYING	KLONOPIN	S				
DRUG INTERACTION	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jul-2010	7480480	NON-EXPEDITED	N		US-PFIZER INC-2007082444	35 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	CHANTIX	S		every day		PFIZER
DRUG INTERACTION	LEXAPRO	S				
RESTLESSNESS	LEXAPRO	S				
EMOTIONAL DISORDER						
FEELING ABNORMAL						
HEADACHE						
INSOMNIA						
POOR QUALITY SLEEP						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jul-2010	7481721	NON-EXPEDITED	N		US-PFIZER INC-2007088152		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	CHANTIX	S				PFIZER
ANGER	LEXAPRO	S				
ABNORMAL DREAMS						
IRRITABILITY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jul-2010	7482283	NON-EXPEDITED	N		US-PFIZER INC-2007091840	46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SOMNOLENCE	CHANTIX	S	ORAL			PFIZER
	LEXAPRO	S				
	LEXAPRO	S				
	NEXIUM	C				
	FLEXERIL	C				
	VALIUM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jul-2010	7509896	EXPEDITED (15-DAY)	Y	HO	1000015028	66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HAEMOGLOBIN DECREASED	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL; 30 MG (20 MG, 1 IN 1 D), ORAL		
HAEMATOCRIT DECREASED	GABAPENTIN	C				
WHITE BLOOD CELL COUNT INCREASED	SIMVASTATIN	C				
OVERDOSE	VERAPAMIL HYDROCHLORIDE	C				
	LISINOPRIL	C				
	LEVOTHROID	C				
	OMEPRAZOLE	C				
	TEMAZEPAM	C				
	HYDROCODONE	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Jul-2010	7483614	NON-EXPEDITED	N		US-PFIZER INC-2007097486		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	CHANTIX	S				PFIZER
AGITATION	LEXAPRO	S				
ANGER						
IRRITABILITY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2010	6790883	NON-EXPEDITED	Y	OT	US-PFIZER INC-2008020292	53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	CHANTIX	S	ORAL			PFIZER
FATIGUE	VALTREX	C				
HYPERPHAGIA	LODINE	C				
ABDOMINAL DISCOMFORT	ZANTAC	C				
MALAISE	TRAZODONE HYDROCHLORIDE	C				
DIZZINESS	LEXAPRO	S				
DRUG INTERACTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2010	7487523	EXPEDITED (15-DAY)	N	DE	A0870970A	48 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LAMICTAL	S				GLAXOSMITHKLINE
DEPENDENCE	LEXAPRO	S				
Intentional drug misuse	FENTANYL	S				
DEPRESSION						
LOSS OF CONSCIOUSNESS						
WITHDRAWAL SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2010	7488682	NON-EXPEDITED	Y		US-PFIZER INC-2008010870	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	CHANTIX	S	ORAL			PFIZER
EMOTIONAL DISORDER	WELLBUTRIN XL	S				
DISTURBANCE IN ATTENTION	LEXAPRO	S				
NERVOUSNESS	GLUCOSAMINE	C				
CRYING	ACETYLSALICYLIC ACID	C				
NAUSEA	ALL OTHER THERAPEUTIC PRODUCTS	C				
DIZZINESS	ALL OTHER THERAPEUTIC PRODUCTS	C				
DEPRESSION	DIGESTIVES, INCL ENZYMES	C				
HEADACHE	CALCIUM	C				
	ASACOL	C				
	OMEPRAZOLE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2010	7489171	NON-EXPEDITED	Y	DE,OT	US-PFIZER INC-2008015811		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	CHANTIX	S				PFIZER
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2010	7489894	NON-EXPEDITED	N		US-PFIZER INC-2008021014	62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	CHANTIX	S				PFIZER
VITAMIN B12 DEFICIENCY	LEVOTHYROXINE SODIUM	C				
VITAMIN D DEFICIENCY	LISINOPRIL	C				
DRUG INTERACTION	ZETIA	C				
	INSULIN NOS	C				
	VITAMIN D	C				
	LUMIGAN	C	OPHTHALMIC			
	CICLOSPORIN	C				
	CYMBALTA	C				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2010	7497317	DIRECT	N			50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Muscle twitching	LEXAPRO	S	ORAL	20MG DAILY PO		
Anorgasmia						
Marital problem						
Paranoia						
Thinking abnormal						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2010	7492551	NON-EXPEDITED	N		US-PFIZER INC-2008023419	46 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	CHANTIX	S				PFIZER
DRUG INEFFECTIVE	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2010	7492962	NON-EXPEDITED	Y	OT	US-PFIZER INC-2008025093		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	CHANTIX	S				PFIZER
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jul-2010	7495823	NON-EXPEDITED	N		US-PFIZER INC-2008042251	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	CHANTIX	S	ORAL			PFIZER
DEPRESSED MOOD	LORAZEPAM	C				
ANXIETY	ZOLOFT	C				
ACTIVITIES OF DAILY LIVING IMPAIRED	LEXAPRO	S				
ABNORMAL BEHAVIOUR						
ANGER						
EMOTIONAL DISORDER						
FATIGUE						
STRESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jul-2010	7496833	NON-EXPEDITED	N		US-PFIZER INC-2008056324	33 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG SCREEN FALSE POSITIVE	CHANTIX	S				PFIZER
VOMITING	LEXAPRO	S				
NAUSEA	PREVACID	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jul-2010	7500815	NON-EXPEDITED	Y		US-PFIZER INC-2009178746		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABNORMAL DREAMS	CHANTIX	S		1 mg, 2x/day		PFIZER
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jul-2010	7115698	EXPEDITED (15-DAY)	Y	DE,CA	1000008598		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANENCEPHALY	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus	PRENATAL VITAMIN (NOS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jul-2010	7502519	EXPEDITED (15-DAY)	N	OT	US-JNJCH-2010016835		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	BENADRYL	S	ORAL	Text:Several tablets		
BLOOD ALCOHOL ABNORMAL	LEXAPRO	S	UNKNOWN	Text:Unknown		
ROAD TRAFFIC ACCIDENT	ALCOHOL	S	ORAL	Text:Two glasses of wine		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jul-2010	7530644	EXPEDITED (15-DAY)	Y	OT	1000015233		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HOMICIDE	LEXAPRO	S	ORAL	ORAL		
SUICIDE ATTEMPT	ZYPREXA	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jul-2010	7505674	EXPEDITED (15-DAY)	Y	OT	US-ASTRAZENECA-2010SE33504	19 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ACCIDENTAL OVERDOSE	SEROQUEL	S	ORAL			ZENECA
MANIA	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL		3 DAY	
	LEXAPRO	S	ORAL			
	VICODIN	S	UNKNOWN			
	XANAX	S	UNKNOWN			
	ALCOHOL	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jul-2010	7506682	NON-EXPEDITED			US-MYLANLABS-2009S1015568	24 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
YAWNING	LEXAPRO	S	ORAL			ALPHAPHARM
Lacrimation increased	TRAMADOL HYDROCHLORIDE	S	ORAL			ALPHAPHARM
	VICODIN	C				
	TRAZODONE	C	ORAL			
	TRAZODONE	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jul-2010	7388754	EXPEDITED (15-DAY)	N	HO	1000013528	53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
UTERINE LEIOMYOMA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
BLOOD POTASSIUM DECREASED	LEXAPRO	S	ORAL	(10 MG, EVERY OTHER DAY), ORAL		
ANAEMIA	EXFORTE HCT	C				
DIZZINESS	METOPROLOL TARTRATE	C				
FATIGUE	NEXIUM	C				
UTERINE HAEMORRHAGE	PALGIC	C				
OEDEMA PERIPHERAL	ASPIRIN (81 MILLIGRAM)	C				
ASPARTATE AMINOTRANSFERASE INCREASED	LUTEIN (20 MILLIGRAM)	C				
ALANINE AMINOTRANSFERASE INCREASED	CALCIUM (500 MILLIGRAM)	C				
	FISH OIL	C				
	L-LYSINE	C				
	VITAMIN C	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jul-2010	7507451	EXPEDITED (15-DAY)	Y	HO	US-SANOFI-AVENTIS-2010SA042981		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FAMILIAL TREMOR	MULTAQ	S	ORAL			
DRUG INTERACTION	PROPRANOLOL	S	ORAL			
DEPRESSION	PRIMIDONE	S	ORAL			
FATIGUE	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jul-2010	7535771	EXPEDITED (15-DAY)	Y	DE,OT	1000015221	48 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	(1 IN 1 D), ORAL		
DEPRESSION	FENTANYL CITRATE	S				
CONDITION AGGRAVATED	FENTANYL CITRATE	S	TRANSDERMAL	100 MCG (1 IN 1 D), TRANSDERMAL		
DRUG DEPENDENCE	FENTANYL CITRATE	S	TRANSDERMAL	25 MCG (1 IN 1 D), TRANSDERMAL		
DRUG WITHDRAWAL SYNDROME	LAMICTAL	S				
GUN SHOT WOUND						
Intentional drug misuse						
LOSS OF CONSCIOUSNESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jul-2010	7512161	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010092700	40 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS POSTURAL	LIPITOR	S	ORAL	20 mg, 1x/day		PFIZER
BACK PAIN	CHANTIX	S	ORAL	UNK		PFIZER
ABDOMINAL DISCOMFORT	CHANTIX	S	ORAL	1 mg, 2x/day		PFIZER
NAUSEA	LISINOPRIL	S		20 mg, 1x/day		
VOMITING	LEXAPRO	S	ORAL	20 mg, 1x/day		
ILL-DEFINED DISORDER	HUMALOG	C	SUBCUTANEOUS	20 to 40 units as needed		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jul-2010	7513320	NON-EXPEDITED	N		US-PFIZER INC-2008019934	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
URTICARIA	LIPITOR	S				PFIZER
DRUG HYPERSENSITIVITY	LEXAPRO	S				
	LEXAPRO	S				
	PROTONIX	S				
	MENEST	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jul-2010	7538064	EXPEDITED (15-DAY)	N	OT	DSA_43546_2010		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	ATIVAN	S		DF		
CRYING	LEXAPRO	S		DF		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Jul-2010	7514651	NON-EXPEDITED	N		US-PFIZER INC-2009170707	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NEUROPATHY PERIPHERAL	LIPITOR	S		20 mg, 1x/day		PFIZER
PARAESTHESIA	ACETYLSALICYLIC ACID	S				PFIZER
FATIGUE	LEXAPRO	S		UNK		
ANXIETY	PRILOSEC	C		UNK		
FLUSHING						
PAIN						
PRURITUS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Aug-2010	7507911	EXPEDITED (15-DAY)	N	HO,OT	US-BRISTOL-MYERS SQUIBB COMPANY-15212111	64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PULMONARY EMBOLISM	ABILIFY	S	ORAL			
THROMBOSIS	XANAX	S				
	LEXAPRO	S				
	COUMADIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Aug-2010	7518089	NON-EXPEDITED	N		US-PFIZER INC-2006126634		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD SODIUM DECREASED	NORVASC	S	ORAL			PFIZER
PSORIASIS	BENAZEPRIL	S	ORAL			
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Aug-2010	7521947	NON-EXPEDITED	N		US-PFIZER INC-2009151425	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABDOMINAL PAIN	AMLODIPINE BESYLATE	S		10 mg, UNK		PFIZER
SOMNOLENCE	ATENOLOL	S				
DRUG WITHDRAWAL SYNDROME	LEXAPRO	S				
MALAISE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Aug-2010	7531319	DIRECT	N			31 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	LEXAPRO	S	ORAL	10MG DAILY PO		
MALAISE	LEXAPRO	S				
PRODUCT QUALITY ISSUE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Aug-2010	7513039	EXPEDITED (15-DAY)	Y		1000015018	43 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEADACHE	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D),ORAL		
VOMITING	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D), ORAL		
TINNITUS	CAFFEINE ANHYDROU (TABLETS)	C				
DIZZINESS	PANTOPRAZOLE (TABLETS)	C				
DYSPNOEA	ALPRAZOLAM	C				
FEELING HOT	ISOMETHEPTENE MUCATE (TABLETS)	C				
BLOOD PRESSURE INCREASED	DIPYRONE SODIUM (TABLETS)	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Aug-2010	7522858	EXPEDITED (15-DAY)	N	OT	US-ROXANE LABORATORIES, INC.-2010-RO-00944RO		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	DIGOXIN	S				ROXANE
DRUG INTERACTION	FELDENE	S				
	GABAPENTIN	S				
	FOLIC ACID	S				
	ATENOLOL	S				
	ZYRTEC	S	ORAL			
	TRAMADOL HYDROCHLORIDE	S				
	NORVIR	S				
	FERROUS SULFATE	S				
	DIPHENHYDRAMINE	S				
	LOPERAMIDE	S				
	ATROVENT	S				
	COZAAR	S				
	LEXAPRO	S				
	EPOGEN	S				
	ABILIFY	S				
	CARVEDILOL	S				
	SEROQUEL	S				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Aug-2010	7523535	NON-EXPEDITED	N		US-PFIZER INC-2008022181	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LYRICA	S				PFIZER
FEELING DRUNK	FENTANYL CITRATE	C				
	ZOCOR	C				
	DICLOFENAC	C				
	AMITRIPTYLINE	S				
	KLONOPIN	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Aug-2010	7523956	EXPEDITED (15-DAY)	N	OT	US-MERCK-1007USA03871		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	COZAAR	S	ORAL			MERCK
DRUG INTERACTION	FELDENE	S	UNKNOWN			
	GABAPENTIN	S	UNKNOWN			
	FOLIC ACID	S	UNKNOWN			
	DIGOXIN	S	UNKNOWN			
	ATENOLOL	S	UNKNOWN			
	ZYRTEC	S	ORAL			
	TRAMADOL HYDROCHLORIDE	S	UNKNOWN			
	NORVIR	S	ORAL			
	FERROUS SULFATE	S	UNKNOWN			
	DIPHENHYDRAMINE HYDROCHLORIDE	S	UNKNOWN			
	LOPERAMIDE HYDROCHLORIDE	S	UNKNOWN			
	ATROVENT	S	UNKNOWN			
	LEXAPRO	S	ORAL			
	EPOGEN	S	UNKNOWN			
	ABILIFY	S	UNKNOWN			
	CARVEDILOL	S	UNKNOWN			
	SEROQUEL	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Aug-2010	7541045	EXPEDITED (15-DAY)	N	OT	1000015334	14 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LEUKAEMIA RECURRENT	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Aug-2010	7541047	EXPEDITED (15-DAY)	Y	HO	1000015381	46 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANCREATITIS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1D), ORAL		
HEPATIC STEATOSIS	ERECTILE DYSFUNCTION MEDICATION	C				
	TESTOSTERONE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Aug-2010	7525669	NON-EXPEDITED	Y		US-PFIZER INC-2009170500	30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOAESTHESIA	LYRICA	S		75 mg, 2x/day		PFIZER
	LEXAPRO	S		10 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Aug-2010	7528187	NON-EXPEDITED	Y		US-PFIZER INC-2008069076		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LEXAPRO	S				
	SELZENTRY	S				PFIZER
	ZYPREXA	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Aug-2010	7539192	EXPEDITED (15-DAY)	N	OT	1000015363	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
CONGENITAL AORTIC DILATATION						
CONGENITAL AORTIC VALVE INCOMPETENCE						
Maternal drugs affecting foetus						
MULTIPLE CONGENITAL ABNORMALITIES						
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Aug-2010	7536104	DIRECT	Y			31 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INSOMNIA	LEXAPRO	S	ORAL	DAILY PO		
AGITATION						
ANXIETY						
CRYING						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Aug-2010	7530595	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-15224348		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	ATENOLOL	S				
DRUG INTERACTION	ABILIFY	S				
	FERROUS SULFATE	S				
	FELDENE	S		Capsule		
	GABAPENTIN	S				
	FOLIC ACID	S				
	DIGOXIN	S				
	ZYRTEC	S	ORAL			
	TRAMADOL HYDROCHLORIDE	S				
	NORVIR	S	ORAL			
	DIPHENHYDRAMINE	S				
	LOPERAMIDE	S				
	ATROVENT	S				
	COZAAR	S	ORAL			
	LEXAPRO	S	ORAL			
	EPOGEN	S				
	CARVEDILOL	S				
	SEROQUEL	S				
	LACTOSE	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Aug-2010	7532002	NON-EXPEDITED	Y		US-PFIZER INC-2008033807	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	DILANTIN	S				PFIZER
BLOOD SODIUM INCREASED	LEXAPRO	S	ORAL			
BLOOD POTASSIUM INCREASED						
FATIGUE						
MALAISE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Aug-2010	7543607	EXPEDITED (15-DAY)	Y	OT	DSA_43265_2010	68 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING ABNORMAL	XENAZINE	S	ORAL	(12.5 MG TID ORAL)		
MOVEMENT DISORDER	LEXAPRO	S		(DF), (DF)		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Aug-2010	7522294	EXPEDITED (15-DAY)	N	OT	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2010-BP-08655BP		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	ATROVENT	S				BOEHRINGER INGELHEIM
DRUG INTERACTION	FELDENE	S				
	GABAPENTIN	S				
	FOLIC ACID	S				
	DIGOXIN	S				
	TRAMADOL HYDROCHLORIDE	S				
	NORVIR	S	ORAL			
	ATENOLOL	S				
	ZYRTEC	S	ORAL			
	FERROUS SULFATE	S				
	DIPHENHYDRAMINE	S				
	LOPERAMIDE	S				
	COZAAR	S	ORAL			
	LEXAPRO	S	ORAL			
	EPOGEN	S				
	ABILIFY	S				
	CARVEDILOL	S				
	SEROQUEL	S				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Aug-2010	7533891	EXPEDITED (15-DAY)	N	OT	US-ASTRAZENECA-2010SE35835		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	ATENOLOL	S	UNKNOWN			ZENECA
RASH	SEROQUEL	S	ORAL			
	ATROVENT	S				
	ABILIFY	S				
	CARVEDILOL	S				
	COZAAR	S	ORAL			
	DIGOXIN	S				
	DIPHENHYDRAMINE	S				
	EPOGEN	S				
	FOLIC ACID	S				
	FERROUS SULFATE	S				
	GABAPENTIN	S				
	LOPERAMIDE	S				
	LEXAPRO	S	ORAL			
	NORVIR	S				
	FELDENE	S				
	TRAMADOL HYDROCHLORIDE	S				
	ZYRTEC	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Aug-2010	7455690	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010080715		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	FELDENE	S		UNK		PFIZER
DRUG INTERACTION	GABAPENTIN	S		UNK		PFIZER
	ATENOLOL	S		UNK		PFIZER
	FOLIC ACID	S		UNK		
	DIGOXIN	S		UNK		
	ZYRTEC	S	ORAL	UNK		
	TRAMADOL	S		UNK		
	NORVIR	S	ORAL	UNK		
	FERROUS SULFATE	S		UNK		
	DIPHENHYDRAMINE	S		UNK		
	LOPERAMIDE	S		UNK		
	ATROVENT	S		UNK		
	COZAAR	S	ORAL	UNK		
	LEXAPRO	S	ORAL	UNK		
	EPOGEN	S		UNK		
	ABILIFY	S		UNK		
	CARVEDILOL	S		UNK		
	SEROQUEL	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Aug-2010	7537493	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-10P-163-0662073-00		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RESTLESSNESS	LEXAPRO	S				
LIBIDO INCREASED	NAPROXEN	C				
INITIAL INSOMNIA						
PHOTOPHOBIA						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Aug-2010	7538214	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-10P-163-0660700-00		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	NORVIR	S	ORAL			
DRUG INTERACTION	LEXAPRO	S	ORAL			
	FELDENE	S				
	GABAPENTIN	S				
	FOLIC ACID	S				
	DIGOXIN	S				
	ATENOLOL	S				
	ZYRTEC	S	ORAL			
	TRAMADOL HYDROCHLORIDE	S				
	FERROUS SULFATE	S				
	DIPHENHYDRAMINE	S				
	LOPERAMIDE	S				
	ATROVENT	S				
	COZAAR	S	ORAL			
	EPOGEN	S				
	ABILIFY	S				
	CARVEDILOL	S				
	SEROQUEL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Aug-2010	7544814	DIRECT	Y	HO,DS		48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	ZYVOX	S	INTRAVENOUS	600MG Q12 IV		PFIZER
SEROTONIN SYNDROME	LEXAPRO	S	ORAL	20MG DAILY PO		
PYREXIA	DORIPENEM	C				
LETHARGY	SOMA	C				
TREMOR	POTASSIUM CHLORIDE	C				
HYPOPHAGIA	METHADONE HYDROCHLORIDE	C				
	LOVENOX	C				
	DUONEB	C				
	FLUCONAZOLE	C				
	ZOSYN	C				
	PROTONIX	C				
	NYSTATIN	C				
	ZOFRAN	C				
	NORCO	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Aug-2010	7551802	EXPEDITED (15-DAY)	Y	OT	1000015599		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	LEXAPRO	S	ORAL	SEVERAL TABLETS, ORAL		
BLOOD ALCOHOL ABNORMAL	BENADRYL	S				
ALCOHOL USE	ALCOHOL	S	ORAL	2 GLASSES OF WINE, ORAL		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Aug-2010	7479804	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-14921555	39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PNEUMONIA	ABILIFY	S		5 mg 1/2Q		
HEPATITIS	LAMICTAL	S		25mg bid (1x1wk,bidx2wk)		
ADVERSE DRUG REACTION	LEXAPRO	S	ORAL	(30x2)10mg oral		
CHONDROMALACIA	XANAX	S				
OSTEOARTHRITIS	IMDUR	C				
OBSTRUCTIVE AIRWAYS DISORDER	NEXIUM	C				
UMBILICAL HERNIA	POTASSIUM	C				
	WELLBUTRIN XL	C		1DF=300 units NOS	5 YR	
	LISINOPRIL	C				
	METOPROLOL TARTRATE	C				
	REQUIP	C				
	LYRICA	C				
	EFFEXOR XR	C				
	PROZAC	C				
	PAXIL CR	C				
	GLUCOPHAGE	C				
	ACTOS	C				
	AMARYL	C				
	LOPRESSOR	C				
	NORVASC	C				
	ASA	C				
	MULTI-VITAMIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Aug-2010	7547604	DIRECT	Y	OT		46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	LEXAPRO	S	BUCCAL	10MG 1 TABLET DAILY BUCCAL		
ANXIETY						
Balance disorder						
CONTUSION						
DRUG WITHDRAWAL SYNDROME						
FEELING ABNORMAL						
IMPAIRED WORK ABILITY						
LIMB INJURY						
PAIN IN EXTREMITY						
PARAESTHESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Aug-2010	7548593	DIRECT	N	HO			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PAIN IN JAW	LEXAPRO	S		10 MG TABLET 1 PILL @ NIGHT		
HYPOAESTHESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Aug-2010	7546987	EXPEDITED (15-DAY)	N	OT	B0670309A		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	DIGOXIN	S	UNKNOWN			GLAXOSMITHKLINE
DRUG INTERACTION	ZYRTEC	S	ORAL			GLAXOSMITHKLINE
	FOLIC ACID	S	UNKNOWN			GLAXOSMITHKLINE
	ATENOLOL	S	UNKNOWN			
	TRAMADOL HYDROCHLORIDE	S	UNKNOWN			GLAXOSMITHKLINE
	NORVIR	S	ORAL			
	FERROUS SULFATE	S	UNKNOWN			GLAXOSMITHKLINE
	DIPHENHYDRAMINE	S	UNKNOWN			GLAXOSMITHKLINE
	LOPERAMIDE	S	UNKNOWN			
	ATROVENT	S	UNKNOWN			GLAXOSMITHKLINE
	COZAAR	S	ORAL			
	LEXAPRO	S	UNKNOWN			
	EPOGEN	S	UNKNOWN			
	ABILIFY	S	UNKNOWN			
	CARVEDILOL	S	UNKNOWN			GLAXOSMITHKLINE
	SEROQUEL	S	UNKNOWN			
	FELDENE	S	UNKNOWN			GLAXOSMITHKLINE
	GABAPENTIN	S	UNKNOWN			GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Aug-2010	7567320	EXPEDITED (15-DAY)	N	CA	1000015720	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CLEFT LIP	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
CLEFT PALATE						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Aug-2010	7554189	DIRECT	N	OT		60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S				
BLOOD CHOLESTEROL INCREASED						
EMOTIONAL DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Aug-2010	7550074	EXPEDITED (15-DAY)	Y	OT	US-SANOFI-AVENTIS-2010SA048398	22 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SOMNAMBULISM	AMBIEN	S	ORAL			
ROAD TRAFFIC ACCIDENT	LEXAPRO	S	UNKNOWN			
HAND FRACTURE	SEROQUEL	S	UNKNOWN			
SLEEP-RELATED EATING DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Aug-2010	7550098	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010103404		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	ZOLOFT	S		UNK		PFIZER
SEROTONIN SYNDROME	LEXAPRO	S		UNK		
JOINT LOCK	WELLBUTRIN	S		UNK		
DRUG INEFFECTIVE						
FEELING ABNORMAL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Aug-2010	7550341	NON-EXPEDITED	N		US-PFIZER INC-2010099772		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	CHANTIX	S		UNK		PFIZER
SOMNOLENCE	VALPROIC ACID	S		UNK		
CONSTIPATION	LEVETIRACETAM	S		UNK		
	PHENOBARBITAL	S		UNK		
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Aug-2010	7550667	EXPEDITED (15-DAY)	Y	OT	US-ABBOTT-10P-163-0663761-00	35 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION, VISUAL	LEXAPRO	S	ORAL			
HALLUCINATION, AUDITORY	WELLBUTRIN XL	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Aug-2010	7554183	DIRECT	N	DE		44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S				
GUN SHOT WOUND						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Aug-2010	7552124	NON-EXPEDITED	N	OT	US-PFIZER INC-2010102775		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	ZOLOFT	S		UNK	2920 DAY	PFIZER
DRUG INEFFECTIVE	LEXAPRO	S		UNK		
	WELLBUTRIN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Aug-2010	7557389	DIRECT	N	DE		43 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	CHANTIX	S				PFIZER
PERSONALITY CHANGE	LEXAPRO	S				FOREST
MOOD SWINGS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Aug-2010	6962401	EXPEDITED (15-DAY)	Y	OT	1000005412	58 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
THROMBOCYTOPENIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
PETECHIAE	LEXAPRO	S	ORAL	5 MG (10 MG, 1 IN 2 D), ORAL		
ARTHRALGIA	LEXAPRO	S	ORAL	10 MG 910 MG, 1 IN 1 D), ORAL; 20 MG 920 MG, 1 IN 1 D), ORAL		
LYMPHATIC DISORDER	ANTIHYPERINTENSIVE MEDICATION	C				
	METFORMIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Aug-2010	7574326	DIRECT	Y	OT		82 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RESTLESS LEGS SYNDROME	LEXAPRO	S	ORAL	5MGM 1X DAILY ORAL 10MGM 1X DAILY ORAL		FOREST
BREAST TENDERNESS	CARDURA	C				
BREAST SWELLING	TENORMIN	C				
	CRESTOR	C				
	NEXIUM	C				
	ASA	C				
	VALIUM	C				
	FISH OIL	C				
	CENTRUM SILVER	C				
	VITAMIN B12	C				
	VIT E	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Aug-2010	7566278	NON-EXPEDITED			- MYLANLABS-2009S1015505	67 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GAIT DISTURBANCE	LEXAPRO	S	ORAL			ALPHAPHARM
TREMOR	METOPROLOL TARTRATE	S	ORAL			
OSTEOPOROSIS	LISINOPRIL	S	ORAL			
FALL	VITAMINS NOS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Aug-2010	7572302	DIRECT	N	RI		63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEAR	LEXAPRO	S		10MG 1 DOSE		
DECREASED ACTIVITY						
DYSPEPSIA						
FEELING ABNORMAL						
HYPOPHAGIA						
INSOMNIA						
MALAISE						
SUICIDAL IDEATION						
UNEVALUABLE EVENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Aug-2010	7579043	EXPEDITED (15-DAY)	N	HO	1000015932	77 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NORMAL PRESSURE HYDROCEPHALUS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D) ORAL		
DRY MOUTH						
PRODUCTIVE COUGH						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Sep-2010	7491654	EXPEDITED (15-DAY)	Y	DE,OT	US-ABBOTT-10P-163-0657612-00	19 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	VICODIN	S		Unknown		
ACCIDENTAL OVERDOSE	VICODIN	S		Accidental overdose: unknown dose		
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL	Accidental overdose: unknown dose		
	SEROQUEL	S	ORAL			
	SEROQUEL	S	ORAL	Accidental overdose: unknown dose		
	SEROQUEL	S				
	XANAX	S		Unknown		
	XANAX	S		Accidental overdose: unknown dose		
	ALCOHOL	S	ORAL			
	TRAZODONE HYDROCHLORIDE	C				
	ULTRAM	C	ORAL			
	IMITREX	C	ORAL			
	SKELAXIN	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Sep-2010	7576023	DIRECT	Y	OT		34 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TACHYCARDIA	LEXAPRO	S	ORAL	10 MG QD PO		
AGITATION						
ANORGASMIA						
ATRIAL FIBRILLATION						
ERECTILE DYSFUNCTION						
RESTLESSNESS						
VENTRICULAR EXTRASYSTOLES						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Sep-2010	7581902	EXPEDITED (15-DAY)	Y	OT	1000015929		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
PANCYTOPENIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Sep-2010	7410072	NON-EXPEDITED	N		A0858789A	30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INCREASED APPETITE	LAMICTAL	S	UNKNOWN			GLAXOSMITHKLINE
WEIGHT INCREASED	WELLBUTRIN	S	UNKNOWN			GLAXOSMITHKLINE
	LEXAPRO	S	ORAL	20MG Per day		
	AMBIEN	S	UNKNOWN			
	KLONOPIN	S	UNKNOWN			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Sep-2010	7580227	DIRECT	N	DE		29 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	SEROQUEL	S				
CARDIAC ARREST	LEXAPRO	S				
	CLONAZEPAM	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Sep-2010	7504275	EXPEDITED (15-DAY)		HO	1000014950	62 YR	Male	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PSYCHOTIC DISORDER	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
SALIVARY HYPERSECRETION	OMEPRAZOLE	C				
SOMNOLENCE	OCTREOTIDE ACETATE	C				
TREMOR	ATENOLOL	C				
MEMORY IMPAIRMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Sep-2010	7574534	NON-EXPEDITED	N		A0865079A	41 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	REQUIP	S	ORAL			GLAXOSMITHKLINE
VOMITING	LEXAPRO	S	ORAL	10MG Per day	6 DAY	
DRUG INTERACTION						
HYPERHIDROSIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Sep-2010	7575310	EXPEDITED (15-DAY)	Y	OT	US-ASTRAZENECA-2010SE40565	22 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ROAD TRAFFIC ACCIDENT	SEROQUEL	S	ORAL			ZENECA
SOMNAMBULISM	AMBIEN	S	ORAL			
HAND FRACTURE	LEXAPRO	S				
SLEEP-RELATED EATING DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2010	7578662	EXPEDITED (15-DAY)	Y	OT	US-WYE-H04065608	31 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEPATITIS	PROTONIX	S		unknown		WYETH
	LEXAPRO	S	ORAL			LUNDBECK
	LEXAPRO	S				LUNDBECK
	CLONAZEPAM	S		0.5 mg prn		UNKNOWN
	HYDROCHLOROTHIAZIDE	C		unknown		UNKNOWN
	LABETALOL	C		unknown		UNKNOWN

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2010	7540965	EXPEDITED (15-DAY)	Y		1000015295	67 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GASTRIC DISORDER	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
METASTASES TO STOMACH						
NAUSEA						
OVARIAN NEOPLASM						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2010	7579254	NON-EXPEDITED	N		US-WYE-H07957709	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIARRHOEA	PRISTIQ EXTENDED RELEASE	S	ORAL	unknown	15 DAY	WYETH
DYSPEPSIA	LUNESTA	S	ORAL	3-4.5 mg		SEPRACOR
MIDDLE INSOMNIA	LEXAPRO	S	ORAL	unknown	15 DAY	LUNDBECK

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2010	7579395	NON-EXPEDITED	N		US-WYE-H08251709	29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	PRISTIQ EXTENDED RELEASE	S	ORAL			WYETH
WEIGHT DECREASED	PRISTIQ EXTENDED RELEASE	S				WYETH
HEADACHE	LEXAPRO	S	UNKNOWN	unspecified		LUNDBECK
ANXIETY	XANAX	C				
CONDITION AGGRAVATED	INSULIN NOS	C				UNKNOWN
NASOPHARYNGITIS						
PANIC ATTACK						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2010	7579512	NON-EXPEDITED	N		US-WYE-H08528409	42 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	PRISTIQ EXTENDED RELEASE	S	ORAL			WYETH
INSOMNIA	LEXAPRO	S				LUNDBECK
ANXIETY	LEXAPRO	S			3 DAY	LUNDBECK
IRRITABILITY	TRAZODONE HYDROCHLORIDE	C				UNKNOWN

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2010	7579557	NON-EXPEDITED	N		US-WYE-H08654109	34 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MYALGIA	PRISTIQ EXTENDED RELEASE	S	ORAL			WYETH
PALPITATIONS	LEXAPRO	S				LUNDBECK
ANXIETY	NIACIN	C				WYETH
FEELING JITTERY	ACETYLSALICYLIC ACID	C				UNKNOWN

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2010	7579773	NON-EXPEDITED	Y		US-WYE-H08744109	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	PRISTIQ EXTENDED RELEASE	S	ORAL			WYETH
SLEEP DISORDER	LEXAPRO	S				LUNDBECK
MIDDLE INSOMNIA	LEXAPRO	S			1 WEEK	LUNDBECK
FEELING OF BODY TEMPERATURE CHANGE	TOPROL XL	C				
NAUSEA	TAMOXIFEN CITRATE	C				UNKNOWN
ANXIETY	PLAQUENIL	C				
HOT FLUSH						
HYPERHIDROSIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2010	7580045	NON-EXPEDITED	N		US-WYE-H08917509	23 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	LYBREL	S	ORAL		15 DAY	WYETH
ABDOMINAL PAIN LOWER	LEXAPRO	S	UNKNOWN	unknown	8 DAY	LUNDBECK
UTERINE PAIN						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2010	7580653	EXPEDITED (15-DAY)	N	OT	A0880541A		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	WELLBUTRIN	S	UNKNOWN			GLAXOSMITHKLINE
FEELING ABNORMAL	ZOLOFT	S	UNKNOWN			
JOINT LOCK	LEXAPRO	S	UNKNOWN			
DRUG INTERACTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2010	7587843	DIRECT				50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALCOHOL USE	LEXAPRO	S		5 MG ONCE/DAY		
AMNESIA						
LOSS OF CONSCIOUSNESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2010	7594334	DIRECT	N	RI		36 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COGNITIVE DISORDER	LEXAPRO	S	ORAL	10MG DAILY PO	5 YR	
AMNESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Sep-2010	7605042	EXPEDITED (15-DAY)	Y	OT	1000016072	22 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SOMNAMBULISM	LEXAPRO	S				
ROAD TRAFFIC ACCIDENT	ZOLPIDEM	S				
HAND FRACTURE	SEROQUEL	S				
SLEEP-RELATED EATING DISORDER	THYROID MEDICATION NOS	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Sep-2010	7544243	NON-EXPEDITED	N	OT	US-PFIZER INC-2010100615		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEDATION	SERTRALINE HYDROCHLORIDE	S	ORAL	12.5 mg, UNK	3 DAY	PFIZER
ACTIVITIES OF DAILY LIVING IMPAIRED	PROZAC	S		UNK		
ANXIETY	WELLBUTRIN	S	ORAL	UNK		
ABNORMAL DREAMS	LEXAPRO	S	ORAL	UNK		
	PAXIL	S	ORAL	UNK		
	CYMBALTA	S	ORAL	UNK		
	ELAVIL	S		UNK		
	REMERON	S	ORAL	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Sep-2010	7583732	EXPEDITED (15-DAY)	N	OT	US-JNJCH-2010020550		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	ZYRTEC	S	ORAL	Text:Unknown		
DRUG INTERACTION	DIPHENHYDRAMINE	S	UNKNOWN	Text:Unknown		
	FOLIC ACID	S	UNKNOWN	Text:Unknown		
	ATENOLOL	S	UNKNOWN	Text:Unknown		
	TRAMADOL	S	UNKNOWN	Text:Unknown		
	DIGOXIN	S	UNKNOWN	Text:Unknown		
	NORVIR	S	ORAL	Text:Unknown		
	FERROUS SULFATE	S	UNKNOWN	Text:Unknown		
	LOPERAMIDE	S	UNKNOWN	Text:Unknown		
	ATROVENT	S	UNKNOWN	Text:Unknown		
	COZAAR	S	ORAL	Text:Unknown		
	LEXAPRO	S	ORAL	Text:Unknown		
	EPOGEN	S	UNKNOWN	Text:Unknown		
	ABILIFY	S	UNKNOWN	Text:Unknown		
	CARVEDILOL	S	UNKNOWN	Text:Unknown		
	SEROQUEL	S	UNKNOWN	Text:Unknown		
	FELDENE	S	UNKNOWN	Text:Unknown		
	GABAPENTIN	S	UNKNOWN	Text:Unknown		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Sep-2010	7584389	NON-EXPEDITED	Y	OT	US-PFIZER INC-2009290029	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LYRICA	S		UNK		PFIZER
HOSTILITY	LEXAPRO	S	ORAL	10 mg, 1x/day		
	WELLBUTRIN	S	ORAL	150mg am and 100mg pm, 2x/day		
	LUNESTA	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Sep-2010	7584813	NON-EXPEDITED	Y		US-PFIZER INC-2009308963	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VISUAL IMPAIRMENT	LYRICA	S		75, twice daily		PFIZER
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Sep-2010	7585725	NON-EXPEDITED	N		US-PFIZER INC-2010087665		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	LYRICA	S		50 mg, in the evening		PFIZER
WEIGHT INCREASED	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Sep-2010	7588535	NON-EXPEDITED	Y		US-WYE-H10542509		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME	PRISTIQ EXTENDED RELEASE	S	ORAL		5 DAY	WYETH
PARAESTHESIA	LEXAPRO	S		weaned off		LUNDBECK
PARAESTHESIA ORAL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Sep-2010	7589829	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-10P-163-0670468-00	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nodule	HUMIRA	S				
CONTUSION	LEXAPRO	S				
	AMBIEN CR	C				
	MULTI-VITAMIN	C				
	FLAXSEED OIL	C				
	VITAMIN D	C				
	LACTOBACILLUS ACIDOPHILUS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Sep-2010	7610103	EXPEDITED (15-DAY)	N	CA	1000016171	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
ANOMALOUS PULMONARY VENOUS CONNECTION						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Sep-2010	7655868	NON-EXPEDITED	N	HO	DKLU1063423	31 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	SABRIL	S				
	LEXAPRO	S				
	KEPPRA	S				
	LAMICTAL	S				
	CLONAZEPAM	S				
	MEBENDAZOLE	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2010	7587747	EXPEDITED (15-DAY)	Y	HO,OT	1000016024	50 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AMNESIA	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
AGGRESSION						
Ataxia						
SOMNOLENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2010	7592048	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2010-BP-10009BP	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERHIDROSIS	MOBIC	S	ORAL			BOEHRINGER INGELHEIM
MUSCULOSKELETAL STIFFNESS	LEXAPRO	S	ORAL	10 mg		
ABDOMINAL PAIN UPPER	LEXAPRO	S	ORAL	5 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2010	7612531	EXPEDITED (15-DAY)	N	DE	1000016234	67 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
LOSS OF CONSCIOUSNESS						
TOXICITY TO VARIOUS AGENTS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Sep-2010	7593546	NON-EXPEDITED	N		US-WYE-H10763509	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEADACHE	PRISTIQ EXTENDED RELEASE	S	ORAL		6 DAY	WYETH
DIZZINESS	PRISTIQ EXTENDED RELEASE	S				WYETH
HYPERHIDROSIS	LEXAPRO	S				LUNDBECK
DRUG INEFFECTIVE	RAMIPRIL	C				UNKNOWN
	CHOLESTYRAMINE	C				UNKNOWN

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Sep-2010	7594139	NON-EXPEDITED	N		US-WYE-H12141709	71 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PAIN IN EXTREMITY	PRISTIQ EXTENDED RELEASE	S	ORAL		15 DAY	WYETH
INSOMNIA	PRISTIQ EXTENDED RELEASE	S	ORAL		2 DAY	WYETH
FEELING HOT	LEXAPRO	S		unknown	6 WEEK	LUNDBECK
ARTHRALGIA	LEXAPRO	S		"1/2" amt unknown	2 DAY	LUNDBECK
DRUG WITHDRAWAL SYNDROME	DIOVAN	S		unknown		NOVARTIS
PALPITATIONS	DIAZEPAM	S		unknown		UNKNOWN
	LIPITOR	S		unknown		
	TRAMADOL	C		unknown		UNKNOWN

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Sep-2010	7595249	NON-EXPEDITED	N	OT	US-ASTRAZENECA-2009SE29840		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	SEROQUEL	S	ORAL			ZENECA
DYSKINESIA	ZOLOFT	S				
DIARRHOEA	TRAZODONE HYDROCHLORIDE	S	UNKNOWN			
TREMOR	DOXEPIN HYDROCHLORIDE	S	UNKNOWN			
MUSCLE TWITCHING	MIRTAZAPINE	S	UNKNOWN			
NIGHTMARE	PRISTIQ EXTENDED RELEASE	S	ORAL			
DRUG INEFFECTIVE	EFFEXOR XR	S	ORAL			
DRUG EFFECT DECREASED	WELLBUTRIN	S	UNKNOWN			
DRY MOUTH	ZYPREXA	S	UNKNOWN			
AGEUSIA	LEXAPRO	S				
CONSTIPATION	PAROXETINE HYDROCHLORIDE	S				
DECREASED APPETITE	CYMBALTA	S				
	PAXIL	S				
	PROZAC	S				
	DEPAKOTE	S	UNKNOWN			
	VITAMINS	C				
	FISH OIL	C				
	IMODIUM	C				
	KAOLIN\PECTIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Sep-2010	7595259	NON-EXPEDITED	Y	HO	US-ASTRAZENECA-2010SE33313		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL FIBRILLATION	SEROQUEL	S	ORAL			ZENECA
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Sep-2010	7597105	EXPEDITED (15-DAY)	Y	HO	US-ROCHE-727275	83 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPEECH DISORDER	BEVACIZUMAB	S	INTRAVENOUS	LAST DOSE PRIOR SAE: 26 AUGUST 2010		ROCHE
	ERLOTINIB HYDROCHLORIDE	S	UNKNOWN			ROCHE
	CARDURA	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	DULCOLAX (BISACODYL)	S	UNKNOWN			
	IBUPROFEN	S	UNKNOWN			
	NOVOLOG	S	UNKNOWN	REPORTED AS NOVALOG		
	SALMETEROL	S	UNKNOWN			
	SIMVASTATIN	S	UNKNOWN			
	TYLENOL	S	UNKNOWN			
	ZOFRAN	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Sep-2010	7598134	NON-EXPEDITED			US-ASTRAZENECA-2010SE 14712	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABDOMINAL DISCOMFORT	SEROQUEL XR	S	ORAL			ASTRAZENECA
GASTROOESOPHAGEAL REFLUX DISEASE	SEROQUEL XR	S	ORAL			ASTRAZENECA
WEIGHT INCREASED	SEROQUEL XR	S	ORAL			ASTRAZENECA
	LEXAPRO	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Sep-2010	7598774	NON-EXPEDITED	N		US-WYE-H12886310	33 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	PRISTIQ EXTENDED RELEASE	S	ORAL			WYETH
ANXIETY	LEXAPRO	S	ORAL			LUNDBECK
PALPITATIONS	LEXAPRO	S	ORAL			LUNDBECK
INSOMNIA	CLONAZEPAM	C				UNKNOWN
	AMBIEN CR	C				SANOFI AVENTIS

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Sep-2010	7598976	NON-EXPEDITED	N		US-WYE-H13405510	69 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE TWITCHING	PRISTIQ EXTENDED RELEASE	S	ORAL			WYETH
	LEXAPRO	S		"tapering off"		LUNDBECK

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Sep-2010	7606584	DIRECT	Y	HO		89 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FALL	LEXAPRO	S				
DYSARTHRIA						
HYPONATRAEMIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Sep-2010	7609986	DIRECT	N			51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	10 MG ONCE A DAY PO		
APPARENT DEATH						
CONDITION AGGRAVATED						
DISTURBANCE IN ATTENTION						
FATIGUE						
FEAR						
NAUSEA						
NERVOUSNESS						
UTERINE CANCER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Sep-2010	7610915	DIRECT	N	RI		33 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEXUAL DYSFUNCTION	LEXAPRO	S				FOREST
LOSS OF LIBIDO						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Sep-2010	7605667	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010116226	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ARTHRALGIA	LYRICA	S	ORAL	75 mg, 2x/day		PFIZER
VITAMIN D DECREASED	LEXAPRO	S		UNK		
RASH	PEPCID	C		UNK		
PRURITUS	UNSPECIFIED INGREDIENT	C		UNK		
SCAB	ACIPHEX	C		UNK		
Dry eye	NORVASC	C		UNK		
NASAL DRYNESS	POTASSIUM	C		UNK		
DRY MOUTH	ALLEGRA	C		UNK		
ALOPECIA						
FATIGUE						
FEELING ABNORMAL						
MUSCULOSKELETAL PAIN						
MUSCULOSKELETAL STIFFNESS						
PAIN						
POOR QUALITY SLEEP						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Sep-2010	7548420	EXPEDITED (15-DAY)	Y	DE	AU-ASTRAZENECA-2010SE 38860	55 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	SEROQUEL XR	S	ORAL	300-400 MG DAILY		
COMPLETED SUICIDE	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Sep-2010	7628423	EXPEDITED (15-DAY)	Y	DE,HO	1000016374	68 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S		30 MG (30 MG,1 IN 1 D)		
HERPES ZOSTER	GEODON	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL ; 160 MG (2 IN 1 D),ORAL		
NERVOUSNESS	NORTRIPTYLINE HYDROCHLORIDE	C				
GUN SHOT WOUND	XANAX	C				
INTENTIONAL SELF-INJURY						
OVERDOSE						
TONGUE DISORDER						
TRISMUS						
UNEVALUABLE EVENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Sep-2010	7580296	EXPEDITED (15-DAY)	Y	OT	1000015915	57 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG DEPENDENCE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
AGITATION	ZIMOVANE (ZOPICLONE) (ZOPICLONE)	C				
ANXIETY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Sep-2010	7617208	DIRECT	Y	LT		47 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERHIDROSIS	LEXAPRO	S				FOREST
ALCOHOL USE						
FLUSHING						
HEART RATE INCREASED						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Sep-2010	7679703	NON-EXPEDITED	N		US-WYE-H15951510	40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	PRISTIQ EXTENDED RELEASE	S				
DIZZINESS	EFFEXOR XR	S				
HYPERSOMNIA	LEXAPRO	S				
CONDITION AGGRAVATED	NEURONTIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Sep-2010	7619541	DIRECT	Y	OT		56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ELECTROCARDIOGRAM QT PROLONGED	HALDOL	S	ORAL	5 MG AND 0.5 MG Q 4 HOURS PRN ORAL/IM, 8/27-9/1		
	LEXAPRO	S		20 MG DAILY ORAL, 8/26 - 8/31		
	WELLBUTRIN	C				
	ZYPREXA	C				
	MACRODANTIN	C				
	GEODON	C				
	THORAZINE	C				
	ABILIFY	C				
	SYNTHROID	C				
	PREMARIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Sep-2010	7633927	DIRECT	Y	OT			Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG PRESCRIBING ERROR	HYOSCYAMINE SULFATE \METHENAMINE\METHYLENE BLUE\PHENYL SALICYLATE \SODIUM PHOSPHATE, DIBASIC	S				MISSION
CONTRAINDICATION TO MEDICAL TREATMENT	LEXAPRO	S				
LABELLED DRUG-DRUG INTERACTION MEDICATION ERROR						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Sep-2010	7635990	EXPEDITED (15-DAY)	Y	HO	2010003910	83 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPEECH DISORDER	ERLOTINIB HYDROCHLORIDE	S	ORAL	ORAL		
TOXICITY TO VARIOUS AGENTS	BEVACIZUMAB	S	INTRAVENOUS	(975 MG, Q3W), INTRAVENOUS		
APHASIA	CARDURA	S				
	LEXAPRO	S				
	DULCOLAX (BISACODYL)	S				
	IBUPROFEN (IBUPROFEN)	S				
	NOVOLOG	S				
	SALMETEROL	S				
	SIMVASTATIN	S				
	TYLENOL (PARACETAMOL)	S				
	ZOFRAN	S				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Oct-2010	7385671	EXPEDITED (15-DAY)	Y	HO,LT,OT	US-ABBOTT-06P-163-0352074-00	10 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LEXAPRO	S	ORAL			
Toxicity to various agents	DEPAKOTE	C	ORAL	500mg in AM, 1000mg at bedtime		
RHYTHM IDIOVENTRICULAR	SYNTHROID	C	ORAL			
VENTRICULAR EXTRASYSTOLES	LEXAPRO	S	ORAL			
VENTRICULAR TACHYCARDIA	LITHIUM	S	ORAL			
WHITE BLOOD CELL COUNT INCREASED	CLONIDINE	S	ORAL			
HYPOTHYROIDISM	METHYLPHENIDATE	S	ORAL			
PALLOR	OXCARBAZEPINE	S	ORAL			
ABDOMINAL PAIN						
ATRIOVENTRICULAR BLOCK FIRST DEGREE						
CHEST PAIN						
CONDUCTION DISORDER						
DIARRHOEA						
DISORIENTATION						
DIZZINESS						
DRUG LEVEL ABOVE THERAPEUTIC						
ELECTROCARDIOGRAM QRS COMPLEX PROLONGED						
HYPERHIDROSIS						
HYPOPHAGIA						
HYPOTENSION						
MANIA						
PALPITATIONS						
TACHYARRHYTHMIA						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Oct-2010	7541786	EXPEDITED (15-DAY)	Y	DE,OT	US-PFIZER INC-2010099416	68 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	GEODON	S		20 mg, daily		PFIZER
HERPES ZOSTER	GEODON	S		80 mg, 2x/day		PFIZER
DYSKINESIA	GEODON	S				PFIZER
NERVOUSNESS	LEXAPRO	S		30 mg, 1x/day	510 DAY	
	LEXAPRO	S				
	NORTRIPTYLINE	C		50 mg, daily		
	XANAX	C		1 mg twice daily as needed	510 DAY	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Oct-2010	7617395	EXPEDITED (15-DAY)	N	HO	US-SHIRE-SPV1-2010-01703	37 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCULAR WEAKNESS	ADDERALL XR	S	ORAL	20 mg, 1x/day:qd	191 DAY	
TREMOR	NERATINIB	S	ORAL	240 mg, 1x/day:qd		
OFF LABEL USE	ALPRAZOLAM	S	ORAL	.5 mg, As req'd	298 DAY	
	DIFLUNISAL	S	ORAL	500 mg, 1x/day:qd	113 DAY	
	LEXAPRO	S	ORAL	10 mg, 1x/day:qd	205 DAY	
	TAMOXIFEN CITRATE	C				
	COLECALCIFEROL	C				
	VITAMIN B12	C				
	VALTREX	C				
	LORATADINE	C				
	TYLENOL	C				
	IBUPROFEN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7169759	NON-EXPEDITED	Y	OT	1000006883	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
SLEEP DISORDER	VITAMINS	C				
DISTURBANCE IN ATTENTION	CAPRYLIC ACID	C				
PRURITUS	HYALURONIC ACID	C				
FORMICATION						
MANIA						
VISUAL IMPAIRMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7170038	NON-EXPEDITED	Y	HO,OT	1000007855	40 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INTENTIONAL OVERDOSE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
SUICIDE ATTEMPT	ATIVAN	C				
COMA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7170047	NON-EXPEDITED	N	OT	1000008091	70 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	SEE IMAGE		
DIZZINESS	AVAPRO	C				
MENTAL IMPAIRMENT	XANAX	C				
ANGER						
ANTISOCIAL BEHAVIOUR						
ASTHENIA						
BLOOD PRESSURE INCREASED						
DEPRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7624966	EXPEDITED (15-DAY)	Y	DS,LT,OT	US-JNJFOC-20101001719	69 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ACTIVITIES OF DAILY LIVING IMPAIRED	RISPERIDONE	S	ORAL			
Coordination abnormal	IMITREX	S	ORAL			
INCOHERENT	LEXAPRO	S	ORAL			
SERUM SEROTONIN INCREASED	REMERON	S	UNKNOWN			
DRUG EFFECT INCREASED	TRAZODONE HYDROCHLORIDE	S	UNKNOWN			
DRUG PRESCRIBING ERROR	KEPPRA	S	UNKNOWN			
DRUG ADMINISTRATION ERROR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7698686	NON-EXPEDITED	N	OT	1000009842	19 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
ALOPECIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL; 5 MG (5 MG, 1 IN 1 D), ORAL		
	CYMBALTA	C				
	VISTARIL	C				
	YAZ	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7698693	NON-EXPEDITED	Y	DE	1000008823	90 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEATH	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7698694	NON-EXPEDITED	N	DE	1000009312	56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEATH	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7698700	NON-EXPEDITED	N	OT	1000010560	15 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TARDIVE DYSKINESIA	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7698712	NON-EXPEDITED	Y	OT	1000010594	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGGRESSION	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1), ORAL		
	LORTAB	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7698713	NON-EXPEDITED	Y	OT	1000010700	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ELECTROCARDIOGRAM QT PROLONGED	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7698731	NON-EXPEDITED	N	OT	1000010901	78 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RESTLESSNESS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DIZZINESS	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL; 5 MG (5 MG, 1 IN 1 D), ORAL		
BLOOD PRESSURE DECREASED	HYZAAR	C				
HYPERTENSION	TOPROL XL	C				
	ASPIRIN	C				
	COZAAR	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7698734	NON-EXPEDITED	Y	HO	1000011009	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERSENSITIVITY	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	ALBUTEROL	C				
	VISTARIL	C				
	TRAZODONE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7698736	NON-EXPEDITED	N	OT	1000011079	25 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INTENTIONAL OVERDOSE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
SUICIDE ATTEMPT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7698739	NON-EXPEDITED	Y	HO	1000011108	49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
INTENTIONAL OVERDOSE	KLONOPIN	S	ORAL	(15 MG, ONCE), ORAL		
ANXIETY	AMBIEN	C				
FEELING ABNORMAL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7698782	NON-EXPEDITED	Y	OT	1000011282	18 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL; 210 MG (210 MG, 1 IN 1 D), ORAL		
INTENTIONAL OVERDOSE						
SUICIDE ATTEMPT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7698791	NON-EXPEDITED	Y	OT	1000011630	76 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TARDIVE DYSKINESIA	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
PAIN IN JAW	METOCLOPRAMIDE	S	ORAL	(3 IN 1 D), ORAL		
	SPIRONOLACTONE	C				
	DIOVAN	C				
	VYTORIN	C				
	METOPROLOL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7698797	NON-EXPEDITED	N	OT	1000011656	27 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL		
FATIGUE	ADDERALL	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701149	NON-EXPEDITED	Y	OT	1000014382	74 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION	LEXAPRO	S	ORAL	ORAL		
SUICIDAL IDEATION	LAMICTAL	S	ORAL	350 MG (350 MG, 1 IN 1 D), ORAL		
ANGER	DIGOXIN	C				
CONFUSIONAL STATE	COUMADIN	C				
	VIMPAT	C				
	SEROQUEL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701153	NON-EXPEDITED	N	HO	1000014713	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANXIETY	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
PARAESTHESIA	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
INSOMNIA	ATIVAN	C				
BLOOD SODIUM DECREASED	DETROL	C				
BLOOD PRESSURE INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701154	NON-EXPEDITED	N	OT	1000014859		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
SEDATION						
SEXUAL DYSFUNCTION						
WITHDRAWAL SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701183	NON-EXPEDITED	Y	HO	1000014936		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL FIBRILLATION	LEXAPRO	S				
	SEROQUEL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701218	NON-EXPEDITED	Y	OT	1000011725	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SYNCOPE	LEXAPRO	S	ORAL	2.5 MG (2.5 MG,1 IN 1 D),ORAL ; 5 MG (5 MG, 1 IN 1 D),ORAL		
DIZZINESS	LEXAPRO	S	ORAL	SEE IMAGE		
HOT FLUSH						
PARAESTHESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701219	NON-EXPEDITED	Y	OT	1000015444	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANGIOEDEMA	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
URTICARIA	VESICARE	C				
	SIMVASTATIN	C				
	COUMADIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701221	NON-EXPEDITED	Y	OT	1000011751	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GLAUCOMA	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL		
	CLONAZEPAM (0.25 MILLIGRAM, TABLETS)	C				
	AMBIEN CR	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701222	NON-EXPEDITED	N	OT	1000015549	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
NAUSEA	FIORICET	C				
DIZZINESS	TREXIMET	C				
FATIGUE						
HEADACHE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701224	NON-EXPEDITED	N	OT	1000011914	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL ; 1.25 MG (1.25 MG,1 IN 1 D),ORAL		
DEPRESSION	ARMOUR THYROID (THYROID) (30 MILLIGRAM, TABLETS) (THYROID)	C				
LETHARGY	LIPITOR	C				
HEADACHE						
MALAISE						
MENTAL IMPAIRMENT						
RESTLESSNESS						
SOMNOLENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701225	NON-EXPEDITED	Y	OT	1000011924		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TARDIVE DYSKINESIA	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701229	NON-EXPEDITED	N	OT	1000011971	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
INSOMNIA	SYNTHROID (0.1 MILLIGRAM)	C				
ANXIETY						
INCREASED APPETITE						
PANIC ATTACK						
SWOLLEN TONGUE						
VISUAL IMPAIRMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701233	NON-EXPEDITED	N	OT	1000012025	37 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PARKINSONISM	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL		
DYSTONIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701236	NON-EXPEDITED	N	OT	1000012153		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PSYCHOTIC DISORDER	LEXAPRO	S	ORAL	ORAL		
AMNESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701238	NON-EXPEDITED	Y	OT	1000012423		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	LEXAPRO	S	ORAL	ORAL		
	DEPLIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701251	NON-EXPEDITED	N	DE	1000012425	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701509	NON-EXPEDITED	Y	OT	1000008238		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701510	NON-EXPEDITED	Y	HO	1000008348	29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANCREATITIS	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701519	NON-EXPEDITED	N	OT	1000009071	20 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	PROVENTIL (INHALANT)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701527	NON-EXPEDITED	N	HO	1000009263	26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANCREATITIS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
HEPATITIS	ADVAIR (INHALANT)	C				
	ALBUTEROL (INHALANT)	C				
	MULTI-VITAMIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701530	NON-EXPEDITED	N	OT	1000009315	15 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
JUDGEMENT IMPAIRED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701552	NON-EXPEDITED	N	HO	1000009507		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	LEXAPRO	S	ORAL	SEE IMAGE		
DIZZINESS	LAMICTAL	S	ORAL	100 MG EVERY MORNING (100 MG, 1 IN 1 D), ORAL; 200 MG QHS (200 MG, 1 IN 1 D), ORAL		
AGITATION	SEROQUEL	S	ORAL	(1 IN 1 D), ORAL		
SWELLING FACE	WELLBUTRIN	S	ORAL	150 MG (150 MG, 1 IN 1 D), ORAL		
SUICIDAL IDEATION	RISPERDAL	S	ORAL	1 MG (0.5 MG, 2 IN 1 D), ORAL		
CONFUSIONAL STATE	ZYRTEC-D	C				
AKATHISIA						
HYPOMANIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701554	NON-EXPEDITED	Y	OT	1000009519	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
HOSTILITY	WELLBUTRIN	S	ORAL	250 MG (2 IN 1 D), ORAL		
	LYRICA	S				
	LUNESTA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701555	NON-EXPEDITED	N	HO	1000009544	79 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING ABNORMAL	LEXAPRO	S	ORAL	ORAL		
ASTHENIA	HIGH BLOOD PRESSURE MEDICATION NOS	C				
BLOOD SODIUM DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7701559	NON-EXPEDITED	Y	OT	1000009575	19 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	LANTUS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7702136	NON-EXPEDITED	N	HO	1000012673	66 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
URINARY TRACT INFECTION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
NAUSEA	XANAX (0.25 MMILLIGRAM, TABLETS)	C				
DIZZINESS	TOPROL (50 MILLIGRAM,TABLETS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7702166	NON-EXPEDITED	Y	HO	1000012757	15 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSTONIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7702173	NON-EXPEDITED	N	OT	1000012939	38 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EXTRAPYRAMIDAL DISORDER	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7702187	NON-EXPEDITED	Y	OT	1000012964	76 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SYNCOPE	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
CONTUSION	LORAZEPAM	S				
HYPERTENSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7702195	NON-EXPEDITED	N	HO	1000013165	76 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD SODIUM DECREASED	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	LEVODOPA	C				
	CARBIDOPA	C				
	RITALIN	C				
	RAMIPRIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7702221	NON-EXPEDITED	N	OT	1000013822	53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TYPE 2 DIABETES MELLITUS	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7702703	NON-EXPEDITED	Y	OT	1000014963	24 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
INTENTIONAL OVERDOSE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7702731	NON-EXPEDITED	Y	OT	1000014083	30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S		10 MG (10 MG, 1 IN 1 D)		
	XANAX	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7702737	NON-EXPEDITED	N	OT	1000014108	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL		
SUICIDAL IDEATION	PREVACID	C				
DRUG INEFFECTIVE	SIMVASTATIN	C				
	LEVOTHYROXINE	C				
	LUNESTA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7702759	NON-EXPEDITED	N	HO	1000014202	27 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DEPRESSION						
ERECTILE DYSFUNCTION						
FATIGUE						
LIBIDO DECREASED						
PARAESTHESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7702788	NON-EXPEDITED	Y	OT	1000014329	18 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SLEEP DISORDER	LEXAPRO	S	ORAL	ORAL		
ATRIOVENTRICULAR DISSOCIATION						
SELF INJURIOUS BEHAVIOUR						
SUICIDE ATTEMPT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7746948	NON-EXPEDITED	N	OT	1000012534		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	LEXAPRO	S	ORAL	ORAL		

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2010	7747399	NON-EXPEDITED	Y	HO	1000009395	81 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOAESTHESIA ORAL	LEXAPRO	S	ORAL	SEE IMAGE		
HYPOAESTHESIA	XANAX	C				
RASH	TOPROL XL	C				
	ASPIRIN	C				
	CARDIZEM	C				
	COLACE	C				
	MIRALAX	C				
	SLOW-MAG	C				
	CENTRUM	C				
	ASACOL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2010	7657447	EXPEDITED (15-DAY)	Y	OT	1000016644	68 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL		
HYPOTENSION	VIAGRA	S	ORAL	(50 MG,AS REQUIRED),ORAL		
SYNCOPE	SIMVASTATIN	C				
	PLAVIX (CLOPIDOGREL) (CLOPIDOGREL)	C				
	LISINOPRIL	C				

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Oct-2010	7546370	EXPEDITED (15-DAY)	Y	OT	1000015445	29 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL		
Balance disorder	TYLENOL WITH CODEINE	C				
FALL	KLONOPIN	C				
DIZZINESS	HCTZ	C				
HYPONATRAEMIA	POTASSIUM	C				
	TENORMIN	C				
	PHENERGAN	C				
	OMEPRAZOLE	C				
	BENADRYL	C				
	TYLENOL	C				
	ASPIRIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Oct-2010	7653177	DIRECT	N	OT		39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ADVERSE DRUG REACTION	LEXAPRO	S	ORAL	1 ONE DAILY PO		
DIARRHOEA						
FEELING ABNORMAL						
WEIGHT DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Oct-2010	7663147	EXPEDITED (15-DAY)	N	OT	1000016679		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PHYSICAL ASSAULT	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
SEXUAL ABUSE						

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Oct-2010	7601980	EXPEDITED (15-DAY)	N	HO	A0882338A	64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	FLOLAN	S	INTRAVENOUS			GLAXOSMITHKLINE
SUBDURAL HAEMATOMA	FLOLAN	S	INTRAVENOUS			GLAXOSMITHKLINE
FALL	ASPIRIN	S	ORAL	81MG Per day		GLAXOSMITHKLINE
IMPAIRED DRIVING ABILITY	LEXAPRO	S	UNKNOWN			
	ZOLOFT	C	UNKNOWN			
	ASTELIN	C	NASAL	137MCG Unknown		GLAXOSMITHKLINE
	CRESTOR	C	ORAL	5MG Unknown		
	MULTI-VITAMIN	C	ORAL	1TAB Per day		
	FLONASE	C	NASAL			GLAXOSMITHKLINE
	FUROSEMIDE	C	ORAL	40MG Unknown		GLAXOSMITHKLINE
	IMODIUM	C	ORAL	2MG Unknown		
	POTASSIUM CHLORIDE	C	ORAL	20MEQ Unknown		GLAXOSMITHKLINE
	LETAIRIS	C	ORAL	10MG Unknown		GLAXOSMITHKLINE
	NEXIUM	C	ORAL	4MG Unknown		
	OXYGEN	C		3L As directed		
	RESTASIS	C	OPHTHALMIC			GLAXOSMITHKLINE
	SODIUM CHLORIDE	C				GLAXOSMITHKLINE
	SPIRONOLACTONE	C	ORAL	25MG Unknown		GLAXOSMITHKLINE
	SYNTHROID	C	ORAL	125MCG Unknown		GLAXOSMITHKLINE
	TYLENOL	C	ORAL	325MG Unknown		GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Oct-2010	7610083	EXPEDITED (15-DAY)	Y	OT	1000016199	29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MOOD SWINGS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ALCOHOL USE						
ANGER						
IMPAIRED DRIVING ABILITY						
ROAD TRAFFIC ACCIDENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Oct-2010	7667890	EXPEDITED (15-DAY)	N	HO	1000016738		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CHEST PAIN	LEXAPRO	S				
HYPERHIDROSIS						
PAIN IN EXTREMITY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Oct-2010	7668876	EXPEDITED (15-DAY)	Y	HO	1000016719	22 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GASTRITIS EROSIVE	LEXAPRO	S	ORAL	15 MG (15 MG, 1 IN 1 D), ORAL		
HAEMATEMESIS	NITRAZEPAM (NITRAZEPAM) (NITRAZEPAM)	C				
	DEXAMPHETAMINE (DEXAMPHETAMINE SULFATE) (DEXAMPHETAMINE SULFATE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Oct-2010	7569986	EXPEDITED (15-DAY)	Y	DS,LT,OT	A0877887A	67 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SERUM SEROTONIN INCREASED	IMITREX	S	ORAL	25MG Per day	6 WEEK	GLAXOSMITHKLINE
Coordination abnormal	LEXAPRO	S	ORAL	20MG Per day		
INCOHERENT	REMERON	S	ORAL	7.5MG At night		
ACTIVITIES OF DAILY LIVING IMPAIRED	TRAZODONE	S	ORAL	50MG At night	42 DAY	
DRUG PRESCRIBING ERROR	RISPERDAL	S	ORAL	.25MG At night		
DRUG ADMINISTRATION ERROR	KEPPRA	C	ORAL	250MG Twice per day		GLAXOSMITHKLINE
DRUG EFFECT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Oct-2010	7639136	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15038797	24 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PREGNANCY	BUSPAR	S				BRISTOL MYERS SQUIBB
LIVE BIRTH	METFORMIN HYDROCHLORIDE	S				BRISTOL MYERS SQUIBB
	PROVIGIL	S		tablet		
	LEVOTHYROXINE	S				
	LEXAPRO	S				
	NASONEX	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Oct-2010	7660515	EXPEDITED (15-DAY)	Y	DS,LT,OT	1000016611	69 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SERUM SEROTONIN INCREASED	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
Coordination abnormal	IMITREX	S	ORAL	25 MG (25 MG, 1 IN 1 D), ORAL		
INCOHERENT	REMERON	S	ORAL	7.5 MG (7.5 MG, 1 IN 1 D), ORAL		
ACTIVITIES OF DAILY LIVING IMPAIRED	TRAZODONE HYDROCHLORIDE	S	ORAL	50 MG (50 MG, 1 IN 1 D), ORAL		
	RISPERDAL	S	ORAL	.25 MG (.25 MG, 1 IN 1 D), ORAL		
	KEPPRA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Oct-2010	7672593	EXPEDITED (15-DAY)	Y	OT	1000016816	35 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
IMPAIRED DRIVING ABILITY	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
BLOOD ALCOHOL INCREASED	ALCOHOL (ETHANOL)	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Oct-2010	7643314	EXPEDITED (15-DAY)	N	OT	AU-BRISTOL-MYERS SQUIBB COMPANY-15352784	1 DAY	Male	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FOETAL DISTRESS SYNDROME	ABILIFY	S	TRANSPLACENTAL			
PREMATURE BABY	LEXAPRO	S	TRANSPLACENTAL			
Maternal drugs affecting foetus						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Oct-2010	7645793	NON-EXPEDITED	N		US-WYE-H14973210	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME	VENLAFAXINE HYDROCHLORIDE	S	ORAL			WYETH
HYPERHIDROSIS	VENLAFAXINE HYDROCHLORIDE	S	ORAL			WYETH
BLOOD PRESSURE INCREASED	PRISTIQ EXTENDED RELEASE	S	ORAL			WYETH
ANXIETY	PRISTIQ EXTENDED RELEASE	S				WYETH
PANIC ATTACK	LEXAPRO	S	ORAL			LUNDBECK
SOMNOLENCE	LEXAPRO	S	ORAL			LUNDBECK
DRUG EFFECT DECREASED	LEXAPRO	S		dose was reduced in order to taper off		LUNDBECK
APATHY	PREMARIN	C				WYETH
	BUPROPION HYDROCHLORIDE	C				GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Oct-2010	7646390	NON-EXPEDITED	Y		US-WYE-H18305410	56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	PROTONIX	S	ORAL			WYETH
	COUMADIN	S		unspecified dose, once daily		
	COUMADIN	S				
	LEXAPRO	S	ORAL			LUNDBECK
	VITAMINS NOS	C				UNKNOWN

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Oct-2010	7665305	DIRECT	Y	DS,OT		57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MEMORY IMPAIRMENT	LEXAPRO	S	ORAL	60 MG DAILY ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Oct-2010	7670105	DIRECT	Y	DE		47 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	20MG 1 DAILY P.O.		
GUN SHOT WOUND						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Oct-2010	7739453	EXPEDITED (15-DAY)	N	CA	1000016968	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR HYPOPLASIA	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
CONGENITAL PULMONARY VALVE ATRESIA						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Oct-2010	7764850	NON-EXPEDITED	Y	OT	DSA_41897_2009	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	WELLBUTRIN	S	ORAL	(150 MG EVERY MORNING AND 100 MG EVERY EVENING ORAL)		
HOSTILITY	LEXAPRO	S	ORAL	(10 MG QD ORAL)		
	LYRICA	S		(DF)		
	LUNESTA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Oct-2010	7651036	NON-EXPEDITED	N		US-WYE-H17330910		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME	PRISTIQ EXTENDED RELEASE	S		unspecified		WYETH
HEADACHE	LEXAPRO	S		unspecified		LUNDBECK

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Nov-2010	7238723	EXPEDITED (15-DAY)	Y	DE	1000010771	29 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	5 MG (5 MG,1 IN 1 D), ORAL ; 10 MG (10 MG,1 IN 1 D),ORAL		
DRUG EFFECT DECREASED	EFFEXOR	S	ORAL	SEE IMAGE		
	ZOLOFT (SERTRALINE) (SERTRALINE)	C				
	ERYACNE (ERYTHROMYCIN) (GEL) (ERYTHROMYCIN)	C				
	HERBS (HERBALS NOS W/ VITAMINS NOS) (HERBALS NOS W/VITAMINS NOS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Nov-2010	7674391	DIRECT	N	DE,OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	EFFEXOR	S		SAMPLE CAPSULES		
	CYMBALTA	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Nov-2010	7575852	EXPEDITED (15-DAY)	N	HO,OT	1000015338	80 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
MANIA	ALLOPURINOL	C				
HOSTILITY	BABY ASPIRIN (ACETYLSALICYLIC ACID) (ACETYLSALICYLIC ACID)	C				
AGGRESSION	POTASSIUM (POTASSIUM) (POTASSIUM)	C				
RESTLESSNESS	AMILONDE (AMLODIPINE) (AMLODIPINE)	C				
COMPULSIVE SHOPPING						
PARANOIA						
REFUSAL OF TREATMENT BY PATIENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Nov-2010	7653381	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010134762	41 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL BEHAVIOUR	ZOLOFT	S	ORAL	100 mg, UNK		PFIZER
KNEE ARTHROPLASTY	LEXAPRO	S	ORAL	20mg, one and a half pill daily		
SURGERY	CYMBALTA	S	ORAL	60 mg, 1x/day		
DRUG INEFFECTIVE	WELLBUTRIN	S	ORAL	UNK		
FATIGUE						
SOMNOLENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Nov-2010	7654182	NON-EXPEDITED	N		US-ABBOTT-10P-163-0654328-00	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EAR INFECTION	BIAXIN	S	OTHER			
FATIGUE	LEXAPRO	S	ORAL			
ANXIETY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Nov-2010	7678916	DIRECT	N			25 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	LEXAPRO	S	ORAL	20MG QAM PO		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Nov-2010	7635535	EXPEDITED (15-DAY)	N	HO	1000016469	93 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	LEXAPRO	S	ORAL	2.5 MG (2.5 MG,1 IN 1 D),ORAL		
MALAISE	TEMAZEPAM	C				
DYSPNOEA	PANTOPRAZOLE SODIUM	C				
CONVULSION	PROCHLORPERAZINE (PROCHLORPERAZINE) (PROCHLORPERAZINE)	C				
FAECAL INCONTINENCE	PERINDOPRIL (PERINDOPRIL) (PERINDOPRIL)	C				
	CRANBERRY (ASCIORBIC ACID) (ASCORBIC ACID)	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Nov-2010	7664659	EXPEDITED (15-DAY)	N	OT	1000012211	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S	ORAL	520 MG (20 MG, 1 IN 1 D) ORAL		
RETINAL DETACHMENT	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL 2.5 MG (5 MG, QOD), ORAL		
	LAMICTAL	C				
	SIMVASTATIN (10 MILLIGRAM)	C				

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Nov-2010	7613334	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010119896	68 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	VIAGRA	S	ORAL	100 mg, as needed		PFIZER
HYPOTENSION	SIMVASTATIN	C		40 mg, 1x/day (at night)		
SYNCOPE	PLAVIX	C		75 mg, 1x/day (1 in the morning)		
	LORAZEPAM	C		1 or 1.5 as needed		
	RANIBIZUMAB	C		UNK in each eye		
	VITAMIN C	C		500 mg, 1x/day (in the morning)		
	VITAMIN D	C		1000 IU, 1x/day		
	SELENIUM	C		200 mg, 1x/day (in the morning)		
	VITAMINS NOS	C		UNK		
	MAGNESIUM	C		UNK		
	VIAGRA	S	ORAL	50 mg, as needed		PFIZER
	LISINOPRIL	S		10 mg (2 in the morning and 1 at night)		
	LEXAPRO	S	ORAL	20 mg, DAILY		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Nov-2010	7688879	EXPEDITED (15-DAY)	N	HO	1000016988	93 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	2.5 MG (2.5 MG, 1 IN 1 D), ORAL		
NAUSEA	TEMAZEPAM	C				
	PANTOPRAZOLE SODIUM	C				
	PROCHLORPERAZINE (PROCHLORPERAZINE) (PROCHLORPERAZINE)	C				
	PERINDOPRIL (PERINDOPRIL) (PERINDOPRIL)	C				
	CRANBERRY (CRANBERRY) (CRANBERRY)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Nov-2010	7657779	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010139371		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CATARACT	TOVIAZ	S		UNK		PFIZER
	XANAX	S		UNK		PFIZER
	LEXAPRO	S		UNK		
	LEVAQUIN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Nov-2010	8538811	EXPEDITED (15-DAY)	Y	HO	1000017131	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPHINCTER OF ODDI DYSFUNCTION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
	LEXAPRO	S	ORAL	15 MG (15 MG,1 IN 1 D),ORAL		
	IMITREX (SUMATRIPTAN SUCCINATE) (SUMATRIPTAN SUCCINATE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Nov-2010	8268293	NON-EXPEDITED	N		US-KINGPHARMUSA00001-K200801316	38 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEART RATE INCREASED	SKELAXIN	S		UNK		KING
PARAESTHESIA	LEXAPRO	S	ORAL	10 mg, single	1 DAY	
HYPOAESTHESIA	LEXAPRO	S	ORAL	5 mg, qd	2 DAY	
MYDRIASIS	ALLEGRA D-12 HOUR	S		UNK		
PANIC ATTACK	UNSPECIFIED INGREDIENT	S	NASAL	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Nov-2010	7663104	EXPEDITED (15-DAY)	N	CA	A0890306A		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEARING IMPAIRED	LAMICTAL	S				GLAXOSMITHKLINE
Maternal exposure during pregnancy	WELLBUTRIN XL	S		300MG Per day		GLAXOSMITHKLINE
	LEXAPRO	S		20MG Per day		
	LEXAPRO	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Nov-2010	7696554	EXPEDITED (15-DAY)	Y	OT,RI	1000017157	26 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUPRAVENTRICULAR TACHYCARDIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 MG IN 1 D), ORAL		
TROPONIN I INCREASED	UNSPECIFIED INGREDIENT	S				
DIZZINESS						
PALPITATIONS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Nov-2010	7693633	DIRECT	Y			17 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH PRURITIC	ABILIFY	S	ORAL	2 MG Q QM PO		
DRUG ERUPTION	LEXAPRO	S	ORAL	10 MG Q AM PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Nov-2010	7354689	NON-EXPEDITED	N		US-KINGPHARMUSA00001-K200901555		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SLEEP DISORDER	SKELAXIN	S		UNK		KING
MALAISE	LEXAPRO	S		UNK		
ABDOMINAL DISCOMFORT						
BLADDER DISCOMFORT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Nov-2010	7704192	EXPEDITED (15-DAY)	Y	CA	DSA_44277_2010		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEARING IMPAIRED	WELLBUTRIN	S	TRANSPLACENTAL	(300 MG QD TRANSPLACENTAL)		
Maternal drugs affecting foetus	LAMICTAL	S	TRANSPLACENTAL	(DF TRANSPLACENTAL)		
CONGENITAL ANOMALY	LEXAPRO	S	TRANSPLACENTAL	(20 MG QD TRANSPLACENTAL)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Nov-2010	7653073	EXPEDITED (15-DAY)	N	HO,OT	US-BAYER-201038418NA		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	BETASERON	S	SUBCUTANEOUS	Total daily dose: 3 MG	6 MTH	BAYER
HYPERHIDROSIS	AVONEX	C				
BRADYCARDIA	LEXAPRO	S				
EJECTION FRACTION DECREASED	EFFEXOR XR	S				
DEHYDRATION						
HALLUCINATION						
HYPOTENSION						
INFLUENZA LIKE ILLNESS						
MIGRAINE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Nov-2010	7701736	EXPEDITED (15-DAY)	Y	HO	1000017222	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC ARREST	LEXAPRO	S				
ELECTROCARDIOGRAM QT PROLONGED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Nov-2010	7652436	EXPEDITED (15-DAY)	Y	HO	1000016566	80 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ELECTROLYTE IMBALANCE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
FEELING ABNORMAL	HYDROCHLOROTHIAZIDE	C				
RHABDOMYOLYSIS	SELOKEEN (METOPROLOL TARTRATE)	C				
HYPOKALAEMIA	LORAZEPAM	C				
HYPERNATRAEMIA	XALATAN (LATANOPROST) (EYE DROPS)	C				
NAUSEA						
SOMNOLENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Nov-2010	7654377	EXPEDITED (15-DAY)	N	DE,OT	1000016561	65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL, 20 MG (20 MG, 1 IN 1 D), ORAL		
TOXICITY TO VARIOUS AGENTS	XANAX	S	ORAL	1 MG (1 MG, 1 IN 1 D), ORAL		
PULMONARY CONGESTION	SAPHRIS	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
VISCERAL CONGESTION	VICODIN	S	ORAL			
CARDIOMEGALY	TRIAMTERENE (TRIAMTERENE) (TRIAMTERENE)	C				
LEFT VENTRICULAR HYPERTROPHY	ATACAND (CANDESARTAN) (CANDESARTAN)	C				
NEPHROSCLEROSIS	SIMVASTATIN	C				
PNEUMOCONIOSIS	FAMOTIDINE	C				
BIPOLAR I DISORDER						
SELF-MEDICATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Nov-2010	7676191	NON-EXPEDITED	N		A0879073A	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRY MOUTH	WELLBUTRIN SR	S	ORAL	100MG Per day		GLAXOSMITHKLINE
	LEXAPRO	S	ORAL	20MG Per day		
	ELAVIL	C	ORAL	5MG As required		GLAXOSMITHKLINE
	VALIUM	C	ORAL	2.6MG As required		GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Nov-2010	7717260	EXPEDITED (15-DAY)	Y	OT,RI	1000017333		Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FOETAL DISTRESS SYNDROME	LEXAPRO	S	TRANSPLACENTAL	10 MG (10 MG, 1 IN 1 D), TRANSPLACENTAL		
PREMATURE BABY	ABILIFY	S	TRANSPLACENTAL	30 MG (30 MG, 1 IN 1 D), TRANSPLACENTAL		

Maternal drugs affecting foetus

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Nov-2010	7717277	EXPEDITED (15-DAY)	Y	HO	1000017331	93 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	2.5 MG (2.5 MG, 1 IN 1 D), ORAL		
NAUSEA	PANTOPRAZOLE (ANTOPRAZOLE)	C				
MALAISE	CRANBERRY (VACCINIUM)	C				
DYSPNOEA	PERINDOPRIL (PERINDOPRIL) (PERINDOPRIL)	C				
FAECAL INCONTINENCE	PROCHLORPERAZINE MALEATE (PROCHLORPERAZINE MALEATE) (PROCHLORPERAZINE MALEATE)	C				
	TEMAZEPAM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Nov-2010	7754136	EXPEDITED (15-DAY)	Y	OT,RI	1000017321	48 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OSTEONECROSIS	LEXAPRO	S	ORAL	ORAL		
BONE DENSITY DECREASED	EFFEXOR XR	S	ORAL	75 MG, ORAL		
TOOTH EXTRACTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Nov-2010	7377183	EXPEDITED (15-DAY)	Y	OT,RI	1000013334	30 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Balance disorder	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DECREASED APPETITE	INSULIN NOS (INSULIN NOS) (INSULIN NOS)	C				
DIZZINESS						
HEADACHE						
PAIN IN EXTREMITY						
SEDATION						
SOMNOLENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Nov-2010	7722407	DIRECT	Y	HO,LT,RI		17 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	LEXAPRO	S	ORAL	10MG QD PO		
Intentional overdose	WELLBUTRIN	S	ORAL	150 QD PO		
ANXIETY	ADDERALL XR	S		15MG QD	18 MTH	

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Nov-2010	7722568	DIRECT	Y	LT,OT		49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALCOHOL USE	LEXAPRO	S		25 MG. 1X DAILY		
OVERDOSE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Nov-2010	7679864	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20101105032		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CATARACT	LEVAQUIN	S	UNKNOWN			
	TOVIAZ	S	UNKNOWN			
	XANAX	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Nov-2010	7680422	EXPEDITED (15-DAY)	N	HO	A0894413A	43 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL BEHAVIOUR	WELLBUTRIN	S	ORAL			GLAXOSMITHKLINE
KNEE ARTHROPLASTY	ZOLOFT	S	ORAL	100MG Unknown		
DRUG INEFFECTIVE	LEXAPRO	S	ORAL	30MGD per day		
FATIGUE	CYMBALTA	S	ORAL	60MG Per day		
SOMNOLENCE	METHADONE HYDROCHLORIDE	C				GLAXOSMITHKLINE
ARTHROPATHY						
DEPRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Nov-2010	7724367	EXPEDITED (15-DAY)	Y	DS,LT,OT	2010SP059735	67 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG PRESCRIBING ERROR	REMERON	S	ORAL	7.5 MG;QD;PO		
DRUG ADMINISTRATION ERROR	IMITREX	S	ORAL	25 MG;PRN;PO ; 25 MG;QD;PO		
SERUM SEROTONIN INCREASED	LEXAPRO	S	ORAL	20 MG;QD;PO		
Coordination abnormal	TRAZODONE HYDROCHLORIDE	S	ORAL	50 MG;QD;PO		
SPEECH DISORDER	RISPERDAL	S	ORAL	.25 MG;PO		
ACTIVITIES OF DAILY LIVING IMPAIRED	KEPPRA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Nov-2010	7662935	EXPEDITED (15-DAY)	Y	HO,LT	1000016673	22 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIO-RESPIRATORY ARREST	LEXAPRO	S				
VENTRICULAR ARRHYTHMIA	LEXAPRO	S				
	LAMOTRIGINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Nov-2010	7727858	EXPEDITED (15-DAY)	Y	OT,RI	1000017404		Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BURNING SENSATION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
DIARRHOEA	ANTIHYPERTENSIVES (ANTIHYPERTENSIVES) (ANTIHYPERTENSIVES)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Nov-2010	7733410	EXPEDITED (15-DAY)	Y	DE	1000017441		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RENAL FAILURE ACUTE	LEXAPRO	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Nov-2010	7733431	EXPEDITED (15-DAY)	N	HO,OT,RI	1000017337	71 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	SEE IMAGE		
	DILTIAZEM (DILTIAZEM HYDROCHLORIDE) (DILTIAZEM HYDROCHLORIDE)	C				
	SIMVASTATIN	C				
	ZYRTEC (CETIRIZINE) (10 MILLIGRAM, TABLETS) (CETIRIZINE)	C				
	RAMIPRIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Nov-2010	7733445	EXPEDITED (15-DAY)	Y	OT,RI	1000017390		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CATARACT	LEXAPRO	S				
	TOVIAZ	S				
	XANAX	S				
	LEVAQUIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Nov-2010	7685107	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20101106647		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ENCEPHALOPATHY	FENTANYL	S	TRANSDERMAL			
CONFUSIONAL STATE	XANAX	S	UNKNOWN			
BREAKTHROUGH PAIN	SEROQUEL	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Nov-2010	7687630	NON-EXPEDITED	N	OT	US-PFIZER INC-2010153602	45 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LYRICA	S	ORAL	100mg		PFIZER
PAIN	LYRICA	S				PFIZER
DISTURBANCE IN ATTENTION	LEXAPRO	S	ORAL	60 mg, UNK		
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Dec-2010	7741606	EXPEDITED (15-DAY)	N	DE	1000017495		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RENAL FAILURE	LEXAPRO	S	ORAL	(1 IN 1 D),ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Dec-2010	7741655	EXPEDITED (15-DAY)	Y	OT,RI	1000017481	19 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Dec-2010	7743061	DIRECT	N	HO		33 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	LEXAPRO	S	ORAL	10 MG ONCE PER DAY ORAL, PILL		FOREST
DISSOCIATIVE FUGUE						
MANIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Dec-2010	7743755	EXPEDITED (15-DAY)	N	CA	1000017521	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal drugs affecting foetus	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
PERSISTENT FOETAL CIRCULATION	PAXIL	S	TRANSPLACENTAL	TRANSPLACENTAL		
PATENT DUCTUS ARTERIOSUS	ZOLOFT	S	TRANSPLACENTAL	TRANSPLACENTAL		
MULTIPLE CONGENITAL ABNORMALITIES	PROZAC	S	TRANSPLACENTAL	TRANSPLACENTAL		
NEONATAL RESPIRATORY DISTRESS SYNDROME	EFFEXOR	S	TRANSPLACENTAL	TRANSPLACENTAL		
SEPSIS NEONATAL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Dec-2010	7756360	DIRECT				36 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AKATHISIA	LEXAPRO	S	ORAL	10MG DAILY PO		FOREST
AGGRESSION	CLONAZEPAM	C				
ANGER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Dec-2010	7703555	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20101202533		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	INVEGA	S	ORAL			
DEPRESSION	LEXAPRO	S				
SOMNOLENCE						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Dec-2010	7703741	EXPEDITED (15-DAY)	N	OT	US-BAYER-2010-003121	79 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
URINARY TRACT DISORDER	ACETYLSALICYLIC ACID	S		UNK UNK, Q1MON		BAYER
VISION BLURRED	FESOTERODINE	S	ORAL	8 mg, UNK	5 DAY	
CONSTIPATION	ALPRAZOLAM	S		UNK UNK, PRN		
DRY MOUTH	SIMVASTATIN	S		UNK UNK, Q1MON		
	LEXAPRO	S				
	SEROQUEL	S		UNK UNK, Q1MON		
	FISH OIL	S		UNK UNK, Q1MON		BAYER
	VITAMIN D	S		UNK UNK, Q1MON		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2010	7339797	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010026726	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LYRICA	S		50 mg, 3x/day		PFIZER
THYROID DISORDER	LYRICA	S	ORAL	UNK		PFIZER
MANIA	LEXAPRO	S		UNK		
FIBROMYALGIA	LITHIUM	S	ORAL	UNK		
NEURALGIA	ELAVIL	S	ORAL	UNK		
OEDEMA PERIPHERAL	CLONAZEPAM	C		1 mg, UNK		
DRUG INEFFECTIVE	KLONOPIN	C	ORAL	UNK		
CONSTIPATION						
GENERAL PHYSICAL CONDITION ABNORMAL						
INSOMNIA						
MICTURITION FREQUENCY DECREASED						
PAIN IN EXTREMITY						
WEIGHT INCREASED						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2010	7454553	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2007014600	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LYRICA	S		50 mg, 3x/day		PFIZER
BLADDER DISORDER	LEXAPRO	S				
ABDOMINAL DISTENSION						
ABDOMINAL PAIN						
EYE PAIN						
VISION BLURRED						
VISUAL IMPAIRMENT						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2010	7712462	EXPEDITED (15-DAY)	N	OT	US-PURDUE-USA-2010-0058201	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	OXYCONTIN	S		80 mg, see text		PURDUE
DRUG DETOXIFICATION	MORPHINE SULFATE	S		UNK UNK, see text		PURDUE
Intentional drug misuse	DIAZEPAM	S		UNK UNK, see text		
PAIN	VICODIN ES	S		UNK UNK, see text		
LETHARGY	SOMA	S		UNK UNK, see text		
SOMNOLENCE	PARAFON FORTE	S		UNK UNK, see text		
	ZANAFLEX	S		UNK UNK, see text		
	KLONOPIN	S		UNK UNK, see text		
	ATIVAN	S		UNK UNK, see text		
	PHENERGAN	S		UNK UNK, see text		
	LEXAPRO	S		UNK UNK, see text		
	RELAFEN	S		UNK UNK, see text		
	NEURONTIN	S		UNK UNK, see text		
	LIDODERM	S		UNK UNK, see text		
	MORPHINE SULFATE	C		UNK UNK, see text		
	REGLAN	C		UNK UNK, see text		
	MORPHINE SULFATE	C		UNK UNK, see text		PURDUE
	LOVASTATIN	C		UNK, see text		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Dec-2010	7723121	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2010173852	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	NEURONTIN	S		600 mg, (12 pills)		PFIZER
DRUG DETOXIFICATION	MORPHINE SULFATE	S		20 mg/ml		
Intentional drug misuse	OXYCONTIN	S		80 mg, UNK		
PAIN	DIAZEPAM	S		10 mg, UNK		
LETHARGY	VICODIN	S		UNK		
SOMNOLENCE	SOMA	S		350 mg, UNK		
	PARAFON FORTE	S		UNK		
	ZANAFLEX	S		4 mg, UNK		
	KLONOPIN	S		1 mg, UNK		
	ATIVAN	S		1 mg, UNK		
	PROMETHAZINE	S		UNK		
	LEXAPRO	S		40 mg, UNK		
	RELAFEN	S		750 mg, UNK		
	LIDODERM	S		5 %		
	MORPHINE SULFATE	C		UNK		
	REGLAN	C		10 mg, UNK		
	MORPHINE SULFATE	C		UNK		
	LOVASTATIN	C		20 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Dec-2010	7753188	EXPEDITED (15-DAY)	Y	OT	2010SP062320	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OEDEMA PERIPHERAL	SAPHRIS	S	SUBLINGUAL	20 MG; HS; SL		
MANIA	WELLBUTRIN	S				
	LEXAPRO	S				
	MAXZIDE	C				
	ALPRAZOLAM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Dec-2010	7766111	DIRECT	N	HO		19 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	15MG EVERY DAY PO		WALGREEN
Balance disorder	GEODON	S	ORAL	40MG EVERY DAY PO		
ADVERSE DRUG REACTION						
CONFUSIONAL STATE						
OVERDOSE						
PHYSICAL ASSAULT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Dec-2010	7794836	EXPEDITED (15-DAY)	Y	OT	AE-1210-401	44 YR	Female	SGP

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	LIDODERM	S				
INCORRECT DOSE ADMINISTERED	OXYCONTIN	S		80 MG		
PAIN	MORPHINE SULFATE	S				
LETHARGY	DIAZEPAM	S				
SOMNOLENCE	VICODIN ES	S				
	SOMA	S				
	PARAFON FORTE	S				
	ZANAFLEX	S				
	KLONOPIN	S				
	ATIVAN	S				
	PHENERGAN	S				
	LEXAPRO	S				
	RELAFEN	S				
	NEURONTIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Dec-2010	7730043	NON-EXPEDITED	N		US-PFIZER INC-2010176017	12 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EJACULATION DELAYED	ZOLOFT	S	ORAL	UNK		PFIZER
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Dec-2010	7765225	EXPEDITED (15-DAY)		LT	1000017780		Male	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGGRESSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Dec-2010	7765942	EXPEDITED (15-DAY)		OT	ACO_20790_2010	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEMIPARESIS	AMPYRA	S	ORAL	10 MG, QD, ORAL, 10 MG, BID, ORAL,		
MULTIPLE SCLEROSIS	LEXAPRO	S				
FATIGUE	VALIUM /00017001/ (DIAZEPAM)	C				
DIZZINESS	ANTIHYPERTENSIVES	C				
VISION BLURRED	COPAXONE /03175301/ (GLATIRAMER ACETATE, MANNITOL	C				
INAPPROPRIATE SCHEDULE OF DRUG ADMINISTRATION	LIPITOR	C				
FEELING ABNORMAL						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2010	7766926	EXPEDITED (15-DAY)	Y	OT,RI	1000017582	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	LEXAPRO	S	ORAL	SEE IMAGE		
NAUSEA	CYMBALTA	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
DIZZINESS	XANAX	C				
MUSCLE TIGHTNESS	PROPRANOLOL	C				
ABNORMAL DREAMS						
AGITATION						
CRYING						
DEPERSONALISATION						
DISCOMFORT						
DISTURBANCE IN ATTENTION						
DRUG WITHDRAWAL SYNDROME						
HEADACHE						
HYPERHIDROSIS						
HYPOAESTHESIA						
INFLUENZA LIKE ILLNESS						
IRRITABILITY						
PARAESTHESIA						
SALIVARY HYPERSECRETION						
SUICIDAL IDEATION						
VERTIGO						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2010	7768223	DIRECT	N	HO		81 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	LEXAPRO	S	ORAL	5 MG 1 TIME ONLY ORAL		FOREST
DIARRHOEA						
LOSS OF CONSCIOUSNESS						
MALAISE						
NAUSEA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2010	7768356	DIRECT		OT		60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	LEXAPRO	S	ORAL	10 MG ONCE DAILY MOUTH		
ABDOMINAL PAIN						
Balance disorder						
DECREASED APPETITE						
DIARRHOEA						
URTICARIA						
VERTIGO						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Dec-2010	7766764	EXPEDITED (15-DAY)	Y	OT,RI	1000017803		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEPATIC FAILURE	LEXAPRO	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Dec-2010	7770465	DIRECT	N	HO,LT,RI		16 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	LEXAPRO	S				
VISUAL IMPAIRMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Dec-2010	7799038	EXPEDITED (15-DAY)	N	DE	1000017830	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG ABUSE	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
CEREBROVASCULAR ACCIDENT	SOMA	S	ORAL	1000 MG (250 MG, 4 IN 1 D), ORAL		
CHEST PAIN	PERCOCET	S	ORAL	5/325 MG TABLETS, ORAL		
LOSS OF CONSCIOUSNESS	VALIUM	S				
WRONG TECHNIQUE IN DRUG USAGE PROCESS	FENTORA	S	BUCCAL	400 MG (400 MG, 1 IN 1 D), BU		
INCORRECT ROUTE OF DRUG ADMINISTRATION	FENTANYL	S	TRANSDERMAL	TRANSDERMAL		
	ZIPSOR	S	ORAL	(25 MG), ORAL		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Dec-2010	7359111	EXPEDITED (15-DAY)	Y	CA,OT,RI	1000012796	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TRANSPOSITION OF THE GREAT VESSELS	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
VENTRICULAR SEPTAL DEFECT	MODAFINIL	S	TRANSPLACENTAL	200 MG (200 MG, 1 IN 1 D),TRANSPLACENTAL		
CARDIAC MURMUR	LEVOTHYROXINE (LEVOTHYROXINE SODIUM) (LEVOTHYROXINE SODIUM)	C				
Maternal drugs affecting foetus	METFORMIN HYDROCHLORIDE	C				
PREMATURE BABY	BUSPAR (BUSPIRONE HYDROCHLORIDE)(BUSPIRONE HYDROCHLORIDE)	C				
APGAR SCORE ABNORMAL	NASONEX (MOMETASONE FUROATE) (MOMETASONE FUROATE)	C				
	OB NATAL (OB NATAL) (OB NATAL)	C				
	XYREM (OXYBATE SODIUM) (OXYBATE SODIUM)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Dec-2010	7744447	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-10P-163-0693390-00	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	VICODIN ES	S				
	LEXAPRO	S				
	NEURONTIN	S				
	OXYCONTIN	C				
	MORPHINE SULFATE	C				
	DIAZEPAM	C				
	SOMA	C				
	PARAFON FORTE	C				
	ZANAFLEX	C				
	KLONOPIN	C				
	ATIVAN	C				
	PHENERGAN	C				
	LEXAPRO	C				
	RELAFEN	C				
	LIDODERM	C		Patch		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Dec-2010	7771661	EXPEDITED (15-DAY)	N	DE	1000017884	27 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ASPHYXIA						
COMPLETED SUICIDE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Dec-2010	7388216	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2010056903	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Thoracic vertebral fracture	CELEBREX	S		UNK		PFIZER
Meniscus injury	EFFEXOR	S		UNK		PFIZER
THYROID DISORDER	LEXAPRO	S		20 mg, 1x/day		
ANXIETY	CYMBALTA	S		UNK		
PANIC ATTACK	SEROQUEL	S		600 mg, 1x/day		
NAUSEA	SEROQUEL	S				
ABDOMINAL PAIN UPPER	TEGRETOL	C		UNK		
DRUG INEFFECTIVE	LOPRESSOR	C		50 mg, 2x/day		
INSOMNIA	NEURONTIN	C		300 mg, 3x/day		
	GLUCOPHAGE	C		850 mg, 2x/day		
	PRILOSEC	C		20 mg, 1x/day		
	DICHLORALPHENAZONE \ISOMETHEPTENE MUCATE	C		UNK		
	LORCET	C		10mg/650mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2011	7342962	EXPEDITED (15-DAY)	N	CA	US-ABBOTT-10P-163-0634234-00	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TRANSPOSITION OF THE GREAT VESSELS	LEXAPRO	S	TRANSPLACENTAL			
VENTRICULAR SEPTAL DEFECT	PROVIGIL	S	TRANSPLACENTAL			
Maternal exposure during pregnancy	LEVOTHYROXINE	C	TRANSPLACENTAL			
CARDIAC MURMUR	METFORMIN HYDROCHLORIDE	C	TRANSPLACENTAL			
	BUSPAR	C	TRANSPLACENTAL			
	NASONEX	C	TRANSPLACENTAL			
	OB NATAL	C	TRANSPLACENTAL			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2011	7747060	EXPEDITED (15-DAY)	Y	HO,OT	AU-ASTRAZENECA-2010SE54938	< 1 DAY	Male	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME NEONATAL	SEROQUEL XR	S	TRANSPLACENTAL	50 MG DAILY STARTED PRE-PREGNANCY STOPPED AT 39/40 WEEKS		
	LAMOTRIGINE	S	TRANSPLACENTAL	200 MG DAILY STARTED AT 11/40 WEEK		
	LEXAPRO	S	TRANSPLACENTAL	10 MG DAILY STARTED PRE-PREGNANCY STOPPED AT 10/40 WEEK		
	VALPROATE SODIUM	S	TRANSPLACENTAL	1000 MG DAILY STARTED PRE-PREGNANCY STOPPED AT 10/40 WEEK		
	FERROUS SULFATE\FOLIC ACID	C	TRANSPLACENTAL	1 TABLET DAILY FROM THE FIRST TRIMESTER		
	FERROUS SULFATE\FOLIC ACID	C	TRANSPLACENTAL	1 TABLET DAILY FROM THE FIRST TRIMESTER		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jan-2011	7790733	EXPEDITED (15-DAY)	N	CA	1000018004	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus						
MULTIPLE CONGENITAL ABNORMALITIES						
PATENT DUCTUS ARTERIOSUS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jan-2011	7795699	DIRECT	N	HO		62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10MG DAILY PO		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jan-2011	7796929	DIRECT	Y				Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONTUSION	LEXAPRO	S	ORAL	5 MG DAILY PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jan-2011	7795437	DIRECT	Y	OT		11 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSIVE SYMPTOM	LEXAPRO	S	ORAL	10 MG QHS PO		FOREST
SUICIDAL IDEATION	ABILIFY	C				
CONDITION AGGRAVATED						
PRODUCT QUALITY ISSUE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jan-2011	7324758	EXPEDITED (15-DAY)	N	HO,OT	US-ROCHE-687974	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OBSTRUCTION	PEGINTERFERON ALFA-2A	S	UNKNOWN	FORM: PRE-FILLED SYRINGE;		ROCHE
INFECTION	PEGINTERFERON ALFA-2A	S	UNKNOWN			ROCHE
HAEMORRHAGE	PEGINTERFERON ALFA-2A	S	UNKNOWN			ROCHE
VASCULAR STENT INSERTION	PEGINTERFERON ALFA-2A	S	UNKNOWN	PATIENT IN WEEK 30 OF TREATMENT		ROCHE
EXOSTOSIS	PEGINTERFERON ALFA-2A	S	UNKNOWN	WEEK 33		ROCHE
OEDEMA PERIPHERAL	PEGINTERFERON ALFA-2A	S	UNKNOWN	WEEK 55		ROCHE
WHITE BLOOD CELL COUNT DECREASED	RIBAVARIN	S	UNKNOWN	NOTE: DIVIDED DOSES; PATIENT RECEIVED RIBASPHERE AND RIBAVIRIN (PAR)		
NERVE INJURY	RIBAVARIN	S	UNKNOWN	DOSAGE REDUCED. IN DIVIDED DOSES; WEEK 55		
DYSPNOEA	LEXAPRO	S	ORAL			
BRONCHITIS	LYRICA	C				
ANAEMIA	FLUTICASONE	C				
CONSTIPATION	SERETIDE	C				
DECREASED APPETITE	SKELAXIN	C				
	VITAMIN B12	C				
	COMBIVENT	C				
	OXYCODONE	C				
	LAMOTRIGINE	C		FREQUENCY: AT BEDTIME		
	MORPHINE	C				
	TRAZODONE	C		FREQUENCY: AT BED TIME		
	LISINOPRIL	C				
	PROMETHAZINE	C				
	FENTANYL PATCH	C				
	OXYCODONE	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jan-2011	7755740	EXPEDITED (15-DAY)	N	OT	A0904404A		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	WELLBUTRIN	S	ORAL			GLAXOSMITHKLINE
DEPRESSION	TIKOSYN	S	UNKNOWN			GLAXOSMITHKLINE
DRUG INTERACTION	LEXAPRO	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jan-2011	7755937	EXPEDITED (15-DAY)	N	DE,OT	US-CEPHALON-2011000113	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG ABUSE	FENTORA	S	BUCCAL			
CEREBROVASCULAR ACCIDENT	FENTORA	S				
CHEST PAIN	LEXAPRO	S			176 DAY	
DRUG PRESCRIBING ERROR	SOMA	S				
	SOMA	S				
	PERCOCET	S				
	PERCOCET	S				
	VALIUM	S				
	FENTANYL	S	TRANSDERMAL			
	FENTANYL	S				
	ZIPSOR	S				
	ZIPSOR	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2011	5837874	EXPEDITED (15-DAY)	Y	OT,RI	S05-USA-03295-01	42 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TARDIVE DYSKINESIA	LEXAPRO	S	ORAL	30 MG (30 MG, 1 IN 1 D), ORAL		
	LEXAPRO	S	ORAL	15 MG (15 MG, 1 IN 1 D), ORAL		
	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
	CLOZAPINE	S	ORAL	300 MG (300 MG, 1 IN 1 D), ORAL		
	CLOZAPINE	S	ORAL	50 MG, (150 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2011	7756565	NON-EXPEDITED	N		US-PFIZER INC-2011005057		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NIGHT SWEATS	PRISTIQ EXTENDED RELEASE	S	ORAL	50 mg, 1x/day		PFIZER
	ZOLOFT	S	ORAL	20 mg, 1x/day		PFIZER
	ZOLOFT	S				PFIZER
	LEXAPRO	S	ORAL	10 mg, 1x/day		
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2011	7756604	NON-EXPEDITED	N		US-PFIZER INC-2011005070		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANXIETY	PRISTIQ EXTENDED RELEASE	S	ORAL	UNK		PFIZER
DRUG INEFFECTIVE	LEXAPRO	S		UNK		
INCREASED APPETITE						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2011	7756655	NON-EXPEDITED	N		US-PFIZER INC-2011004027	67 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANIC ATTACK	PRISTIQ EXTENDED RELEASE	S	ORAL	50 mg, 1x/day		PFIZER
NAUSEA	LEXAPRO	S		UNK		
OFF LABEL USE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2011	7800580	DIRECT	N	HO		14 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANXIETY	LEXAPRO	S	ORAL	10 MG ONCE DAILY PO		
AGITATION						
INSOMNIA						
IRRITABILITY						
SUICIDAL IDEATION						
WEIGHT INCREASED						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jan-2011	7759520	EXPEDITED (15-DAY)	N	OT	US-ROCHE-752271	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
POST-TRAUMATIC STRESS DISORDER	VALIUM	S	ORAL	AT NIGHT		ROCHE
SUFFOCATION FEELING	EFFEXOR	S	ORAL	OTHER INDICATION: PANIC DISORDER; FORM: PROLONGED RELEASE CAPSULE		
FEELING ABNORMAL	EFFEXOR	S	ORAL	DOSE INCREASED		
CEREBRAL DISORDER	EFFEXOR	S	ORAL			
ANXIETY	PROZAC	S	ORAL			
PSYCHOMOTOR HYPERACTIVITY	PROZAC	S	ORAL	DOSE DECREASED		
INSOMNIA	PROZAC	S	ORAL	DOSE DECREASED		
HYPOPHAGIA	ZYPREXA	S	ORAL		2 DAY	
DRUG INTOLERANCE	LEXAPRO	S	ORAL			
DRUG INEFFECTIVE	CALCIUM	C				
DRUG DOSE OMISSION	ERGOCALCIFEROL	C				
WRONG TECHNIQUE IN DRUG USAGE PROCESS	FOLIC ACID	C				
	NIACINAMIDE	C				
	PANTHENOL	C				
	RETINOL	C				
	RIBOFLAVIN	C				
	THIAMINE HYDROCHLORIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jan-2011	7759532	EXPEDITED (15-DAY)	Y	DE,HO	US-ROCHE-752292	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CEREBROVASCULAR ACCIDENT	VALIUM	S	UNKNOWN			ROCHE
CHEST PAIN	PERCOCET	S	ORAL			
LOSS OF CONSCIOUSNESS	LEXAPRO	S	ORAL			
	SOMA	S	ORAL			
	FENTORA	S	UNKNOWN			
	FENTANYL	S	TRANSDERMAL			
	ZIPSOR	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jan-2011	7759887	EXPEDITED (15-DAY)	N	HO,CA	US-ABBOTT-11P-163-0695775-00	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			
MULTIPLE CONGENITAL ABNORMALITIES						
PATENT DUCTUS ARTERIOSUS						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jan-2011	7794355	EXPEDITED (15-DAY)	N	DE,HO	2011010001	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CHEST PAIN	SOMA	S	ORAL	1000 MG 9250 MG, 4 IN 1 D), ORAL		
INCORRECT ROUTE OF DRUG ADMINISTRATION	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
LOSS OF CONSCIOUSNESS	PERCOCET	S	ORAL	5/325 MG, ORAL		
CEREBROVASCULAR ACCIDENT	VALIUM	S				
Intentional drug misuse	FENTORA	S		400 MG (400 MG, 1 IN 1 D)		
	FENTANYL (FENTANYL)	S	TRANSDERMAL	TRANSDERMAL		
	ZIPSOR	S	ORAL	(25 MG) , ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2011	7761748	EXPEDITED (15-DAY)	N	HO,OT	US-PFIZER INC-2011006758	65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BIPOLAR DISORDER	ZOLOFT	S				PFIZER
BREAST CANCER	LEXAPRO	S				
THYROID NEOPLASM	TAMOXIFEN CITRATE	S				
ENDOMETRIAL HYPERTROPHY	CYMBALTA	S				
DEPRESSED MOOD	FEMARA	S				
ALCOHOL USE						
DRUG INEFFECTIVE						
DRUG INTERACTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2011	7813935	EXPEDITED (15-DAY)	Y	OT	DSA_44637_2011		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	BUPROPION HYDROCHLORIDE	S	ORAL	(DF ORAL)		
DEPRESSION	TIKOSYN	S				
DRUG INTERACTION	LEXAPRO	S		(DF)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jan-2011	7763482	EXPEDITED (15-DAY)	N		US-JNJFOC-20101202625		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEXUAL DYSFUNCTION	INVEGA	S	ORAL			
SOMNOLENCE	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2011	7449988	EXPEDITED (15-DAY)	Y	OT	1000014565	54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEAFNESS UNILATERAL	LEXAPRO	S	ORAL	(10 MG (10 MG, 1 IN 1 D), ORAL) (5 MG (5 MG, 1 IN 1 D), ORAL) (2.5 MG (2.5 MG, 1 IN 1 D), ORAL) (10		
DEPRESSION	LYRICA	C				
TINNITUS	NASACORT (TRIAMCINOLONE ACETONIDE) (TRIAMCINOLONE ACETONIDE)	C				
PARAESTHESIA	PROZAC	C				
CHILLS						
DRY MOUTH						
EXAGGERATED STARTLE RESPONSE						
NIGHT SWEATS						
PANIC ATTACK						
TEMPOROMANDIBULAR JOINT SYNDROME						
VISION BLURRED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2011	7805127	DIRECT	N	OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	10 MG DAILY PO	4 YR	
ANXIETY	LEXAPRO	S	ORAL	10 MG DAILY PO	5 YR	
NIGHTMARE						
WITHDRAWAL SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jan-2011	7805762	DIRECT	N	HO		20 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DELUSION	LEXAPRO	S	ORAL	20MG 1 PER DAY PO		
ABNORMAL BEHAVIOUR						
EUPHORIC MOOD						
PSYCHOMOTOR HYPERACTIVITY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jan-2011	7806657	DIRECT	N			47 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AMNESIA	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jan-2011	7806730	DIRECT	N	DS,OT			Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AMNESIA	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jan-2011	7825209	EXPEDITED (15-DAY)	N	DE,HO	2011S1000004	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG ABUSE	ZIPSOR	S		25 MG		
CEREBROVASCULAR ACCIDENT	LEXAPRO	S	ORAL	20 MG; QD; PO		
CHEST PAIN	SOMA	S	ORAL	250 MG; QID; PO		
LOSS OF CONSCIOUSNESS	PERCOCET	S	ORAL	1625 MG; QD; PO		
INCORRECT ROUTE OF DRUG ADMINISTRATION	VALIUM	S				
	FENTORA	S		400 MG; QD		
	FENTANYL	S	TRANSDERMAL	400 MG; QD; TDER		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jan-2011	7422233	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2010070738	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD PRESSURE FLUCTUATION	GEODON	S	ORAL	20 mg daily		PFIZER
BLOOD PRESSURE DECREASED	GEODON	S		80 mg, UNK		PFIZER
ATTENTION DEFICIT/HYPERACTIVITY DISORDER	GEODON	S		100 mg, UNK		PFIZER
PERSONALITY DISORDER	GEODON	S		60 mg, UNK		PFIZER
MAJOR DEPRESSION	GEODON	S		80 mg, 3x/day		PFIZER
BIPOLAR DISORDER	GEODON	S		40 mg, 2x/day		PFIZER
	GEODON	S		40 mg, UNK		PFIZER
	GEODON	S		60 mg, UNK		PFIZER
	GEODON	S		40 mg, 2x/day		PFIZER
	ZOLOFT	S		UNK		PFIZER
	EFFEXOR	S	ORAL	75 mg, daily		PFIZER
	EFFEXOR	S		37.5 mg, in the morning	7 DAY	PFIZER
	EFFEXOR	S		75 mg, UNK		PFIZER
	EFFEXOR	S		150 mg, in the morning		PFIZER
	EFFEXOR	S		75 mg, 2x/day		PFIZER
	EFFEXOR	S		40 mg, 2x/day		PFIZER
	LITHIUM	S		UNK		
	KLONOPIN	S		UNK		
	KLONOPIN	S		1 mg, 2x/day		
	KLONOPIN	S		0.5 mg, 3x/day		
	KLONOPIN	S		1 mg, 3x/day, as needed		
	KLONOPIN	S		0.5 mg, 3x/day		
	LEXAPRO	S		UNK		
	SEROQUEL	S		100 mg at bedtime		
	SEROQUEL	S		50 mg, at bedtime as needed		
	SEROQUEL	S		100 mg, as needed		

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	SEROQUEL	S		200 mg, at night		
	SEROQUEL	S		300 mg, UNK		
	SEROQUEL	S		200 mg, at 6 and 9 at night		
	SEROQUEL	S		200 mg, at night		
	PAXIL	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jan-2011	7809468	DIRECT				45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
POOR QUALITY SLEEP	LEXAPRO	S				
APATHY						
Balance disorder						
CHEST DISCOMFORT						
CONFUSIONAL STATE						
FATIGUE						
FEELING ABNORMAL						
HYPERHIDROSIS						
MEMORY IMPAIRMENT						
PAIN						
PALPITATIONS						
PANIC ATTACK						
PARAESTHESIA						
REBOUND EFFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jan-2011	7765766	NON-EXPEDITED	N		US-PFIZER INC-2011007677	90 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANXIETY	CARDURA	S		UNK		PFIZER
INSOMNIA	LEXAPRO	S		UNK		
DIZZINESS	LASIX	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jan-2011	7809989	DIRECT	N			35 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S	ORAL	10MG ONCE A DAY PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jan-2011	7810011	DIRECT	Y	OT		16 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSTONIA	LEXAPRO	S	ORAL	10MG QAM PO		
AKATHISIA	HALOPERIDOL	S	INTRAVENOUS	5MG, STAT,IV		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2011	7777965	NON-EXPEDITED	N		A0860715A		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANIC ATTACK	WELLBUTRIN	S				GLAXOSMITHKLINE
DRUG INTERACTION	LEXAPRO	S			3 DAY	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2011	7777992	NON-EXPEDITED	N		A0866793A		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GOITRE	WELLBUTRIN	S	UNKNOWN			GLAXOSMITHKLINE
BENIGN NEOPLASM OF THYROID GLAND	LEXAPRO	S	UNKNOWN			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2011	7778009	NON-EXPEDITED	Y		A0871968A		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEADACHE	WELLBUTRIN	S				GLAXOSMITHKLINE
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2011	7817065	EXPEDITED (15-DAY)	Y	CA	1000018277		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CRANIOSYNOSTOSIS	LEXAPRO	S	TRANSPLACENTAL	10 MG (10 MG, 1 IN 1 D), TRANSPLACENTAL , 10 MG (10 MG,1 IN 1 D),TRANSMAMMARY		

Maternal drugs affecting foetus

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2011	7817120	EXPEDITED (15-DAY)	N	OT,RI	1000018285	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DECREASED INTEREST	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
UPPER LIMB FRACTURE	TRILIPIX (FENOFIBRIC ACID) (FENOFIBRIC ACID)	C				
CONFUSIONAL STATE	NORVASC	C				
MUSCLE SPASMS	LISINOPRIL (LISINOPRIL)	C				
DISTURBANCE IN ATTENTION						
FALL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Jan-2011	7811204	DIRECT	N	OT		47 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERHIDROSIS	LEXAPRO	S		ONE A DAY		FOREST
ASTHMA						
DRUG INEFFECTIVE						
DYSPNOEA						
FEELING ABNORMAL						
HEAD BANGING						
INFLUENZA LIKE ILLNESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Jan-2011	7813256	DIRECT	Y	HO		39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GRAND MAL CONVULSION	LEXAPRO	S	ORAL	LEXAPRO 10MG PO QD	1 MTH	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Feb-2011	7825473	EXPEDITED (15-DAY)	Y	LT	1000018533		Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
AGGRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Feb-2011	7816747	DIRECT	N	OT		58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGGRESSION	LEXAPRO	S				
MEMORY IMPAIRMENT	TESTIM	S				
ABNORMAL BEHAVIOUR						
SOCIAL AVOIDANT BEHAVIOUR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Feb-2011	7818269	DIRECT	Y	LT,OT		72 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PLATELET COUNT DECREASED	LEXAPRO	S	ORAL	5 MG PO DAILY		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2011	7820672	DIRECT	N			46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE SPASMS	TRILEPTAL	S				
TEMPOROMANDIBULAR JOINT SYNDROME	LEXAPRO	S				
DRUG INTERACTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2011	7852748	NON-EXPEDITED	N	OT	017873	53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	KEPPRA	S				
CRYING	LEXAPRO	S	ORAL	(10 MG QD ORAL), (5 MG QD ORAL), (2.5 MG, EVERY OTHER DAY ORAL), (10 MG QD ORAL)		
DRY MOUTH	SYNTHROID	C				
THIRST	BABY ASPIRIN	C				
FEELING ABNORMAL						
PAIN						
WEIGHT INCREASED						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2011	7800453	EXPEDITED (15-DAY)	Y	HO	US-CEPHALON-2011000455	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	AMRIX	S	ORAL			
Overdose	TANEZUMAB	S			167 DAY	
HYPOXIA	FIORICET	S			167 DAY	
HYPOVENTILATION	PHENERGAN	S				
RHABDOMYOLYSIS	LEXAPRO	S			2 YR	
RESPIRATORY FAILURE	NORTRIPTYLINE	S				
CONVULSION	LOTREL	S				
COMA	THERA-GESIC	C				
ARRHYTHMIA						
CARDIAC ARREST						
CONFUSIONAL STATE						
HYPOTENSION						
VOMITING						

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Feb-2011	7802733	EXPEDITED (15-DAY)	Y	HO	PHHO2011US01819		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC ARREST	LOTREL	S	ORAL	10/40		NOVARTIS
RESPIRATORY FAILURE	FIORICET	S		UNK	169 DAY	
COMA	PHENERGAN	S				
RHABDOMYOLYSIS	LEXAPRO	S		10 mg, QD		
CONVULSION	NORTRIPTYLINE	S				
ARRHYTHMIA	AMRIX	S				
HYPOTENSION	THERA-GESIC	C		UNK		
CONFUSIONAL STATE	HYDROCHLOROTHIAZIDE	C		UNK		
HYPOVENTILATION	PROZAC	C		40 mg, QD		
HYPOXIA						
INTENTIONAL OVERDOSE						
SUICIDAL IDEATION						
SUICIDE ATTEMPT						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Feb-2011	7824420	DIRECT	N	HO,LT		24 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERSENSITIVITY	LEXAPRO	S		20 MG ONCE DAILY		
DIZZINESS						
HEADACHE						
PARAESTHESIA						
REFUSAL OF TREATMENT BY PATIENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Feb-2011	7841151	EXPEDITED (15-DAY)	Y	OT,RI	1000018608	42 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SLEEP DISORDER	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL		
ANXIETY						
RESTLESSNESS						
SUICIDAL BEHAVIOUR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Feb-2011	7799148	NON-EXPEDITED	N	OT	US-PFIZER INC-2011023117		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OEDEMA PERIPHERAL	NEURONTIN	S	ORAL	600 mg, 3x/day		PFIZER
SWELLING FACE	MIRALAX	S	ORAL	1 Capful at 1300, 1 Capful at 1830		
	SEROQUEL	S	ORAL	50 mg, 2x/day		
	TOPAMAX	S	ORAL	200 mg, 1x/day		
	LEXAPRO	S	ORAL	40 mg, 1x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Feb-2011	7803393	NON-EXPEDITED	N		US-PFIZER INC-2011024094		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	SINEQUAN	S		UNK		PFIZER
	LEXAPRO	S				
	TOFRANIL	S				
	WELLBUTRIN	S				
	PROZAC	S		UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2011	7794136	EXPEDITED (15-DAY)	N	HO	2010P1003456	81 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	FENTANYL	S	TRANSDERMAL	50 MCG/HR; Q 72 HR; TDER, 50 MCG/HR; Q 72 HR; TDER		
ILEUS	FENTANYL	S	TRANSDERMAL	75 MCG/JR; Q 72 HR; TDER		
DEPRESSION	FUROSEMIDE	S	ORAL	40 MG; QD; PO		
ATRIAL FIBRILLATION	LEXAPRO	S	ORAL	20 MG; PO		
BLOOD POTASSIUM DECREASED	SERTRALINE	S		50 MG; QD		
DIZZINESS	PANTOPRAZOLE	C				
FLUID RETENTION	DIAZYDE	C				
	POTASSIUM CHLORIDE	C				
	DETROL LA	C				
	RE DUALVIT PLUS (IRON)	C				
	AMLODIPINE	C				
	MILK OF MAGNESIA	C				
	TYLENOL	C				
	VITAMIN D	C				
	PREV MEDS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2011	7831742	DIRECT	Y	DS		85 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EXTRAPYRAMIDAL DISORDER	LEXAPRO	S	ORAL	20 MG DAILY PO	4 MTH	
DRUG EFFECT DECREASED						
DYSKINESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Feb-2011	7679153	EXPEDITED (15-DAY)	Y	HO	PHHO2010US05532	88 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WHITE BLOOD CELL COUNT INCREASED	ZOLEDRONIC ACID	S	INTRAVENOUS	Double blind	1 DAY	
DELIRIUM	UNSPECIFIED INGREDIENT	S	INTRAVENOUS	Double blind	1 DAY	
FALL	UNSPECIFIED INGREDIENT	S	INTRAVENOUS	Double blind	1 DAY	
URINARY TRACT INFECTION BACTERIAL	METHYLPHENIDATE	S				
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	CELEXA	S				
ENCEPHALOPATHY	DITROPAN	S				
HYPONATRAEMIA	WELLBUTRIN	S				
CEREBROVASCULAR ACCIDENT	OXYCODONE HYDROCHLORIDE	S				
APHASIA	LEXAPRO	S				
	ZYRTEC	S				
	CLINDAMYCIN	S				
	CALCIUM	C				
	VITAMIN D	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Feb-2011	7834561	DIRECT	Y	RI		38 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AMNESIA	LEXAPRO	S	ORAL	20MG AT NIGHT PO		FOREST
APHASIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Feb-2011	7624610	NON-EXPEDITED	N		US-PFIZER INC-2010082389	40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	NEURONTIN	S		UNK		PFIZER
SOMNOLENCE	PRISTIQ EXTENDED RELEASE	S		UNK		PFIZER
DIZZINESS	PRISTIQ EXTENDED RELEASE	S				PFIZER
FATIGUE	EFFEXOR XR	S		UNK		PFIZER
	EFFEXOR XR	S				PFIZER
	LEXAPRO	S		UNK		
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Feb-2011	7812298	NON-EXPEDITED	N	OT	US-PFIZER INC-2011031442	40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MYDRIASIS	PRISTIQ EXTENDED RELEASE	S	ORAL	50 mg, 1x/day		PFIZER
WEIGHT INCREASED	LEXAPRO	S		UNK		
	XANAX	C	ORAL	0.25 mg, as needed		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Feb-2011	7841812	DIRECT	Y	OT,RI		48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RESTLESSNESS	ABILIFY	S		10 MG AT BEDTIME		
AGITATION	LEXAPRO	S		20 MG IN MORNING		
Coordination abnormal						
DISORIENTATION						
DIZZINESS						
PALPITATIONS						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2011	7838311	DIRECT	Y	HO,LT		39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	LEXAPRO	S	ORAL	5MG DAILY PO		
ANGIOEDEMA						
ANXIETY						
AUTOIMMUNE DISORDER						
ENDOCRINE DISORDER						
FORMICATION						
INFECTION						
PRURITUS						
SWOLLEN TONGUE						
THYROID DISORDER						
URTICARIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2011	7859431	EXPEDITED (15-DAY)	N	OT	DSA_44928_2011	39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	WELLBUTRIN	S		DF		
SUICIDAL IDEATION	LEXAPRO	S	ORAL	20 MG, QD, ORAL		
CRYING	TRAZODONE	C				
BIPOLAR DISORDER	TOPAMAX	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2011	7590370	NON-EXPEDITED	N		US-PFIZER INC-2010115950		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEADACHE	ZOLOFT	S		UNK		PFIZER
NAUSEA	PRISTIQ EXTENDED RELEASE	S		50 mg, each morning		PFIZER
CONSTIPATION	PRISTIQ EXTENDED RELEASE	S				PFIZER
HYPERSENSITIVITY	LEXAPRO	S		UNK		
DRUG INEFFECTIVE	VITAMIN C	C				
THERAPEUTIC RESPONSE UNEXPECTED						
WRONG TECHNIQUE IN DRUG USAGE PROCESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2011	7766776	EXPEDITED (15-DAY)	Y	CA	1000017759	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANKYLOGLOSSIA CONGENITAL	LEXAPRO	S	TRANSPLACENTAL	20 MG (20 MG, 1 IN 1 D), TRANSPLACENTAL		
Maternal drugs affecting foetus	PRENATAL VITAMIN (PRENATAL VITAMIN) (PRENATAL VITAMIN)	C				
FACE PRESENTATION	FISH OIL (FISH OIL) (FISH OIL)	C				
APGAR SCORE LOW						
CAESAREAN SECTION						
FEEDING DISORDER NEONATAL						
MECONIUM IN AMNIOTIC FLUID						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2011	7817328	EXPEDITED (15-DAY)	N	OT	A0913841A	40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	WELLBUTRIN	S	UNKNOWN			GLAXOSMITHKLINE
CRYING	LEXAPRO	S	ORAL	20MG Per day		
DRUG INEFFECTIVE	TRAZODONE	C		150MG Per day		
PRODUCT QUALITY ISSUE	TOPAMAX	C				GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2011	7829026	EXPEDITED (15-DAY)	Y	HO	1000018543	36 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NEPHROPATHY TOXIC	LEXAPRO	S	ORAL	40 MG, ONCE, ORAL		
EPILEPSY	FLUPENTIXOL DECANOATE	S	INTRAMUSCULAR	40 MG, INTRAMUSCULAR		
LOSS OF CONSCIOUSNESS	DIAZEPAM (DIAZEPAM)	C				
PARKINSONISM	ATORVASTATIN (ATORVASTATIN)	C				
BODY TEMPERATURE FLUCTUATION	LEVETIRACETAM	C				
EPISTAXIS	METFORMIN HYDROCHLORIDE	C				
OVERDOSE	OLANZAPINE (OLANZAPINE)	C				
DRUG ADMINISTRATION ERROR						
DRUG INEFFECTIVE						
DRUG INTERACTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2011	7854524	EXPEDITED (15-DAY)	Y	HO	2011SP000428	44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Intentional overdose	LUNESTA	S	ORAL	2 MG; HS; ORAL, 60 MG; 1X, ORAL		
SUICIDE ATTEMPT	AMBIEN CR	S		12.5 MG; HS;		
INSOMNIA	XANAX	S				
DRUG INEFFECTIVE	LEXAPRO	S				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2011	7855836	EXPEDITED (15-DAY)	Y	OT,RI	1000018727		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION, VISUAL	LEXAPRO	S				
INTENTIONAL SELF-INJURY						
PAPILLOEDEMA						
VISUAL FIELD DEFECT						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2011	7637187	EXPEDITED (15-DAY)	N	HO	1000016393	89 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
URINARY TRACT INFECTION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
LETHARGY	NAMENDA	C				
Staphylococcus test positive	ARICEPT	C				
HYPERSOMNIA	COZAAR	C				
INSOMNIA	CLONIDINE TRANSDERMAL SYSTEM	C				
ARRHYTHMIA	METHYLPHENIDATE (METHYLPHENIDATE) (METHYLPHENIDATE)	C				
	METOPROLOL SUCCINATE	C				
	OMEPRAZOLE	C				
	OXYTROL (OXYBUTYNIN TRANSDERMAL)(OXYBUTYNIN TRANSDERMAL)	C				
	SEROQUEL (QUETIAPINE FUMARATE) (QUETIAPINE FUMARATE)	C				
	STALEVO(CARBIDOPA, LEVODOPA, ENTACAPONE) (CARBIDOPA, LEVODOPA, ENTACAPONE)	C				
	FLUDROCORTISONE ACETATE (FLUDROCORTISONE ACETATE) (FLUDROCORTISONE ACETATE)	C				
	FINASTERIDE (FINASTERIDE) (FINASTERIDE)	C				
	TPN (TPN) (LIQUID) (TPN)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2011	7861663	EXPEDITED (15-DAY)	Y	DE	1000018747		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PULMONARY OEDEMA	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2011	7826563	EXPEDITED (15-DAY)	N	HO	US-WATSON-2011-01859	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	FIORICET	S	ORAL	25 mg, single	1 DAY	WATSON
SUICIDE ATTEMPT	PHENERGAN	S	ORAL	UNK	1 DAY	
VOMITING	LEXAPRO	S	ORAL	10 mg 1x/day	1 DAY	
HYPOTENSION	PAMELOR	S	ORAL	25 mg, 1x/day	1 DAY	
CONFUSIONAL STATE	AMRIX	S	ORAL	UNK	1 DAY	
HYPOXIA	LOTREL	S	ORAL	10/40		
HYPOVENTILATION	UNSPECIFIED INGREDIENT	S	INTRAVENOUS	every 8 weeks	169 DAY	
RHABDOMYOLYSIS	HYDROCHLOROTHIAZIDE	C	UNKNOWN	UNK		
CONVULSION	MENTHOL\METHYL SALICYLATE	C		UNK		
ARRHYTHMIA						
CARDIAC ARREST						
COMA						
RESPIRATORY FAILURE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2011	7855990	DIRECT	N	DE		56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Feb-2011	7832163	NON-EXPEDITED	N		A0863154A		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRURITUS	LAMICTAL	S	ORAL			GLAXOSMITHKLINE
	LEXAPRO	S	UNKNOWN			
	SEROQUEL	S	UNKNOWN			GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Feb-2011	7833467	NON-EXPEDITED	Y		US-PFIZER INC-2010042881		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEADACHE	GEODON	S		20 mg, UNK		PFIZER
	MIRTAZAPINE	S		15 mg, UNK		
	CLONAZEPAM	S		0.5 mg, UNK		
	LEXAPRO	S		20 mg, UNK		
	BUPROPION	S		300 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2011	7865709	DIRECT	N	DS		77 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FALL	LEXAPRO	S	ORAL	30MG 1 AT NIGHT ORAL		
AMNESIA						
NIGHTMARE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2011	7841423	EXPEDITED (15-DAY)	Y	OT	AU-PFIZER INC-2011045974		Male	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GAMMA-GLUTAMYLTRANSFERASE INCREASED	LIPITOR	S		80 mg, UNK		PFIZER
BLOOD ALKALINE PHOSPHATASE INCREASED	DIPYRIDAMOLE	S		UNK		
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Mar-2011	7846089	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2011048172	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NEPHROLITHIASIS	LIPITOR	S		UNK		PFIZER
HYPERSOMNIA	LEXAPRO	S	ORAL	10 mg, daily	7 DAY	
MYALGIA	LEXAPRO	S	ORAL	20 mg, 1x/day		
OVERDOSE	LEXAPRO	S	ORAL	40 mg, 1x/day		
	LEXAPRO	S	ORAL	20 mg, 1x/day		
	LEXAPRO	S	ORAL	30 mg, 1x/day		
	NADOLOL	C		UNK		
	DEXIDRINE	C		UNK		
	DEXIDRINE	C		UNK		
	ADDERALL	C		UNK		
	PRAVASTATIN	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Mar-2011	7882894	EXPEDITED (15-DAY)	Y	OT,RI	1000019127	35 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CHOKING SENSATION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
SKIN BURNING SENSATION	ALPRAZOLAM (ALPRAZOLAM) (TABLETS) (ALPRAZOLAM)	C				
ABDOMINAL PAIN UPPER	ATENOLOL	C				
TREMOR	AMLODIPINE	C				
HYPERHIDROSIS	HYDROCHLOROTHIAZIDE	C				
DEPRESSION						
HEADACHE						
INSOMNIA						
MALAISE						
TACHYCARDIA						
TINNITUS						
VAGINAL HAEMORRHAGE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2011	7871240	EXPEDITED (15-DAY)	Y	OT,RI	1000018755	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GRAND MAL CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
HYPONATRAEMIA	HYDROCHLOROTHIAZIDE	S	ORAL	12.5 MG (25 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Mar-2011	7878890	DIRECT	N	OT		31 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	1 TABLET DAILY PO		
MANIA						
PATHOLOGICAL GAMBLING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Mar-2011	7857432	NON-EXPEDITED	N		US-PFIZER INC-2010150860	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEADACHE	PRISTIQ EXTENDED RELEASE	S	ORAL	50 mg, 1x/day		PFIZER
SOMNOLENCE	LEXAPRO	S	ORAL	5 mg, 1x/day		
SEDATION	WELLBUTRIN	S	ORAL	100 mg, 1x/day	42 DAY	
	FEMARA	C	ORAL	UNK		
	TAMOXIFEN	C	ORAL	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Mar-2011	7860661	EXPEDITED (15-DAY)	Y	HO,OT	US-VIROPHARMA INCORPORATED-20110303CINRY1852	62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	CINRYZE	S				VIRONPHARMA
LIP SWELLING	LEXAPRO	S				
INFUSION RELATED REACTION	DIAZEPAM	S				
HEREDITARY ANGIOEDEMA	ATENOLOL	S				
DEPRESSION						
INAPPROPRIATE SCHEDULE OF DRUG ADMINISTRATION						
THYROID DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Mar-2011	6792168	EXPEDITED (15-DAY)	N	HO,OT	US-BRISTOL-MYERS SQUIBB COMPANY-13944517	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FIBROMYALGIA	ABILIFY	S		started 7 years ago, took for 5 years	2 YR	
SPINAL COLUMN STENOSIS	LEXAPRO	S				
MANIA	LASIX	C				
TEETH BRITTLE	OXYBUTYNIN	C				
ARTHRALGIA	METOPROLOL TARTRATE	C				
DYSKINESIA	ELAVIL	C				
TOOTH LOSS	FLEXERIL	C				
BACK PAIN	ATARAX	C				
DIPLOPIA	LIPITOR	C				
ARTHRITIS	NEURONTIN	C				
	SAPHRIS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Mar-2011	7867607	NON-EXPEDITED	N		US-PFIZER INC-2011061038		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALOPECIA	PRISTIQ EXTENDED RELEASE	S		UNK		PFIZER
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Mar-2011	7888821	DIRECT	N				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR	LEXAPRO	S		DAILY	5 WEEK	
HEADACHE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Mar-2011	7856094	EXPEDITED (15-DAY)	Y	HO	US-PFIZER INC-2011055565	44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	XANAX	S		UNK		PFIZER
SUICIDE ATTEMPT	LUNESTA	S	ORAL	2 mg, at HS		
INSOMNIA	LUNESTA	S	ORAL	60 mg, single		
	AMBIEN CR	S		12.5 mg, at HS		
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Mar-2011	7871193	EXPEDITED (15-DAY)	Y	HO,OT,RI	1000019025	88 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANAEMIA	LEXAPRO	S	ORAL	ORAL		
HAEMORRHOIDS	SOLIRIS	S	INTRAVENOUS	600 MG (600 MG,1 IN 1 1 WK), INTRAVENOUS (NOT OTHERWISE SPECIFIED); 900 MG (1 IN 2 WK),INTRAVENOUS		
TINNITUS	TRANLORAZEPATE POTASSIUM) (CLORAZEPATE DIPOTASSIUM)	C				
RECTAL HAEMORRHAGE	FOLIC ACID	C				
ERYTHEMA	CENTRUM (MULTIVITAMIN) (MULTIVITAMIN)	C				
SKIN EXFOLIATION	LIPITOR	C				
BREAST CANCER	ARIMIDEX (ANASTROZOLE) (ANASTROZOLE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Mar-2011	7890639	DIRECT	N	DE		49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	AMBIEN	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Mar-2011	7894380	DIRECT	N	OT		49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	LEXAPRO	S	ORAL	10MG 1X DAILY ORAL		FOREST
ABDOMINAL DISTENSION						
ABDOMINAL PAIN						
DIARRHOEA						
FREQUENT BOWEL MOVEMENTS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Mar-2011	7898902	EXPEDITED (15-DAY)	Y	OT	1000019269	20 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERPROLACTINAEMIA	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D), ORAL		
PITUITARY TUMOUR BENIGN	VYVANSE (LISDEXAMFETAMINE) (LISDEXAMFETAMINE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Mar-2011	7901867	EXPEDITED (15-DAY)	N	OT,RI	1000019301	14 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL		
AGITATION	LEXAPRO	S	ORAL	15 MG (15 MG, 1 IN 1 D), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL		
DYSKINESIA	SEROQUEL	S	ORAL	25 MG QAM, 50 MG QPM, ORAL		
BIPOLAR DISORDER	SEROQUEL	S	ORAL	50 MG QAM, 100 MG QPM, ORAL		
DYSTONIA	CLONIDINE (CLONIDINE) (0.1 MILLIGRAM, TABLETS) (CLONIDINE)	C				
BRUXISM						
GRIMACING						
INITIAL INSOMNIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Mar-2011	7878772	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2011067304	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MENTAL IMPAIRMENT	XANAX	S	ORAL	0.5 mg, as needed		PFIZER
TREMOR	LEXAPRO	S	ORAL	10 mg, 1x/day		
HEART RATE INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Mar-2011	7879487	NON-EXPEDITED	N		US-PFIZER INC-2011069659		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	ZOLOFT	S		UNK		PFIZER
DRY MOUTH	LEXAPRO	S		UNK		
DECREASED APPETITE						
LOSS OF LIBIDO						
MALAISE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Apr-2011	7645673	NON-EXPEDITED	N		US-PFIZER INC-US-WYE-H14299410	38 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR	EFFEXOR	S	ORAL	150.0 mg, 2x/day		PFIZER
DRUG INEFFECTIVE	ZOLOFT	S	ORAL	100.0 mg, 1x/day		PFIZER
CHILLS	ZOLOFT	S	UNKNOWN	50.0 mg, 1x/day		PFIZER
	LEXAPRO	S	UNKNOWN	100.0 mg, 1x/day		
	ACETYLSALICYLIC ACID	C	UNKNOWN	81 mg, 1x/day		
	LIPITOR	C	UNKNOWN	30 mg, 1x/day		
	FISH OIL, HYDROGENATED	C	UNKNOWN	UNK		
	GEMFIBROZIL	C	ORAL	600 mg, 2x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Apr-2011	7835700	NON-EXPEDITED	N	OT	US-PFIZER INC-2011038703		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	PROZAC	S		unknown		
DEPRESSION	PROZAC	S				
	CYMBALTA	S		1 DF, single		
	CYMBALTA	S				
	LEXAPRO	S		unknown		
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Apr-2011	7911271	EXPEDITED (15-DAY)	Y	OT	1000019390	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GLAUCOMA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	NAVELBINE (VINORELBINE) (VINORELBINE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Apr-2011	7913406	EXPEDITED (15-DAY)	Y	HO	1000019456	62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	LEXAPRO	S				
LIP SWELLING	CINRYZE	S		500 UNIT (500 UNITS, 1 IN 1 WK)		
INFUSION RELATED REACTION	DIAZEPAM	S				
	ATENOLOL (ATENOLOL)	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Apr-2011	7325793	EXPEDITED (15-DAY)	N	DE,OT	AU-PFIZER INC-2010031875	29 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	ZOLOFT	S		UNK		PFIZER
DEPRESSION	EFFEXOR	S		UNK		
ANXIETY	LEXAPRO	S		5 mg, 1x/day		
CONFUSIONAL STATE	LEXAPRO	S		10 mg, 1x/day		
NERVOUSNESS	FISH OIL	C		UNK		
AGITATION						
FEELING ABNORMAL						
MOOD ALTERED						
RESTLESSNESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Apr-2011	7882958	NON-EXPEDITED	N		US-PFIZER INC-2010035994	38 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR	ZOLOFT	S	ORAL	100 mg, 1x/day		PFIZER
CHILLS	EFFEXOR	S	ORAL	150 mg, 2x/day		PFIZER
DRUG INEFFECTIVE	LEXAPRO	S		UNK		
	LIPITOR	C	ORAL	30 mg, 1x/day		
	GEMFIBROZIL	C	ORAL	600 mg, 2x/day		
	ACETYLSALICYLIC ACID	C	ORAL	81 mg, 1x/day		
	FISH OIL	C		UNK, once a day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Apr-2011	7883156	NON-EXPEDITED	N		US-PFIZER INC-2009284276	35 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERSENSITIVITY	ZOLOFT	S	ORAL	12.5 mg, UNK		PFIZER
SCLERAL DISORDER	ZOLOFT	S	ORAL	12.5 mg, UNK		PFIZER
THYROID DISORDER	LEXAPRO	S		UNK		
FOOD ALLERGY	MULTIVITAMINS	C		UNK		
EYE PRURITUS	FOLIC ACID	C		UNK		
OCULAR HYPERAEMIA	VITAMIN B12	C		UNK		
DRUG HYPERSENSITIVITY						
REACTION TO PRESERVATIVES						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Apr-2011	7886079	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2010074098	62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	XANAX XR	S		UNK, as needed before bedtime		PFIZER
TACHYCARDIA	EFFEXOR XR	S		UNK, once daily		PFIZER
INSOMNIA	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Apr-2011	7908338	DIRECT	N	OT		58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TINNITUS	CYMBALTA	S		30 MG. 1 A DAY		
BLOOD PRESSURE INCREASED	LEXAPRO	S		LEXAPRO 1 A DAY		
DYSURIA						
GASTROINTESTINAL DISORDER						
MALAISE						
PAIN						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Apr-2011	6805354	EXPEDITED (15-DAY)	N	DE,OT	AU-PFIZER INC-AU-WYE-G02474308	17 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME	EFFEXOR	S		75.0 mg, 1x/day		PFIZER
COMPLETED SUICIDE	EFFEXOR	S		75 mg, UNK		PFIZER
MULTIPLE INJURIES	EFFEXOR	S		112.5mg daily		PFIZER
INTENTIONAL SELF-INJURY	EFFEXOR	S		150 mg, 1x/day		PFIZER
AGITATION	EFFEXOR	S		75 mg, 1x/day		PFIZER
SUICIDAL IDEATION	ZOLOFT	S		UNK		PFIZER
CONDITION AGGRAVATED	LEXAPRO	S		5 mg, 1x/day	3 DAY	
ANXIETY	LEXAPRO	S		10 mg, 1x/day		
IMPAIRED DRIVING ABILITY	ERYTHROMYCIN	C		20mg/g 2% gel daily		
ROAD TRAFFIC ACCIDENT	FISH OIL	C		UNK		
ANHEDONIA						
BIPOLAR DISORDER						
BIPOLAR II DISORDER						
COGNITIVE DISORDER						
CONFUSIONAL STATE						
CRYING						
DEPRESSION						
DISTRACTIBILITY						
DISTURBANCE IN ATTENTION						
DRUG EFFECT DECREASED						
DRUG INEFFECTIVE						
FEELING ABNORMAL						
FEELING GUILTY						
FEELING OF DESPAIR						
FRUSTRATION						
IMPULSIVE BEHAVIOUR						
INSOMNIA						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Intentional drug misuse						
MALAISE						
MEMORY IMPAIRMENT						
MENTAL STATUS CHANGES						
MOOD ALTERED						
NERVOUSNESS						
NONSPECIFIC REACTION						
OBSESSIVE THOUGHTS						
PANIC ATTACK						
PSYCHOMOTOR HYPERACTIVITY						
RESTLESSNESS						
SELF ESTEEM DECREASED						
SEXUAL DYSFUNCTION						
SPEECH DISORDER						
THINKING ABNORMAL						
UNEVALUABLE EVENT						

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Apr-2011	7843548	EXPEDITED (15-DAY)	Y	DE,HO	US-CELGENEUS-163-21880-11022573	84 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Plasma cell myeloma	REVLIMID	S	ORAL	25 Milligram		CELGENE
COGNITIVE DISORDER	REVLIMID	S	ORAL	25 Milligram		CELGENE
ENCEPHALOPATHY	REVLIMID	S	ORAL	25 Milligram		
MUSCULOSKELETAL PAIN	DEXAMETHASONE	S	ORAL	40 Milligram		
NAUSEA	DEXAMETHASONE	S	ORAL	40 Milligram		
	HYDROCODONE	S	UNKNOWN			
	FLEXERIL	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	DILAUDID	S	UNKNOWN			
	DILAUDID	S	PARENTERAL	.4 Milligram		
	XANAX	S	UNKNOWN			
	PROTONIX	S	UNKNOWN			
	RIVASTIGMINE	S	UNKNOWN			
	ASPIRIN	C	ORAL	325 Milligram		
	ANTIVIRAL	C	UNKNOWN			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Apr-2011	7184808	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009296613		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	ZOLOFT	S		UNK		PFIZER
DYSKINESIA	TRAZODONE HYDROCHLORIDE	S		UNK		
DIARRHOEA	DOXEPIN HYDROCHLORIDE	S		UNK		PFIZER
TREMOR	PRISTIQ EXTENDED RELEASE	S	ORAL	50 mg, 1x/day		PFIZER
MUSCLE TWITCHING	EFFEXOR XR	S	ORAL	75 mg, 1x/day		PFIZER
NIGHTMARE	MIRTAZAPINE	S		UNK		
DRUG INEFFECTIVE	WELLBUTRIN	S		UNK		
DRUG EFFECT DECREASED	ZYPREXA	S		UNK		
DRY MOUTH	SEROQUEL	S		UNK		
AGEUSIA	LEXAPRO	S		UNK		
CONSTIPATION	PAROXETINE	S		UNK		
DECREASED APPETITE	CYMBALTA	S		UNK		
DIVERTICULITIS	PAXIL	S		UNK		
	PROZAC	S		UNK		
	DEPAKOTE	S		UNK		
	VITAMINS	C		UNK		
	FISH OIL	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Apr-2011	7891138	NON-EXPEDITED	N		US-PFIZER INC-2011073854		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SOMNOLENCE	PRISTIQ EXTENDED RELEASE	S		UNK		PFIZER
FATIGUE	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Apr-2011	7901865	EXPEDITED (15-DAY)	Y	DE	1000019288	53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ASTHMA	LEXAPRO	S	ORAL	ORAL; 30 (30 MG, 1 IN 1 D), ORAL;		
PNEUMONIA	NAFAZODONE	C				
ACCIDENTAL OVERDOSE	TRILEPTAL	C				
BRONCHOSPASM	LAMICTAL	C				
TOXICITY TO VARIOUS AGENTS	XANAX	C				
	CAMPRAL	C				
	ZYRTEC (CEITRIZINE)	C				
	FLONASE	C				
	ROBITUSSIN DM (DEXTROMETHORPHAN, GUAFENESIN)	C				
	FLOVENT HFA (FLUTICASONE PROPIONATE)	C				
	ALBUTEROL HFA (SALBUTAMOL)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Apr-2011	7906872	DIRECT		OT		45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	LEXAPRO	S				
CHEILITIS	SYNTHROID	C				
GINGIVAL DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Apr-2011	7893670	EXPEDITED (15-DAY)	N	OT	US-ASTRAZENECA-2011SE 18638	14 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BIPOLAR DISORDER	SEROQUEL	S	ORAL	25 MG QAM AND 50 MG QPM	0 YR	ZENECA
INSOMNIA	SEROQUEL	S	ORAL	25 MG QAM AND 50 MG QPM	0 YR	ZENECA
DYSTONIA	SEROQUEL	S	ORAL	50 MG QAM AND 100 MG QPM	0 YR	ZENECA
	SEROQUEL	S	ORAL	50 MG QAM AND 100 MG QPM	0 YR	ZENECA
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL		4 MTH	
	LEXAPRO	S	ORAL		4 MTH	
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	CLONIDINE	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Apr-2011	7928288	EXPEDITED (15-DAY)	Y	HO	1000019726	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOXIA	LEXAPRO	S	ORAL	5 MG (5 MG,1 IN 1 D),ORAL		
DYSPNOEA	LORAZEPAM	C				
BLOOD PRESSURE DECREASED						
CHEST DISCOMFORT						
SEROTONIN SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Apr-2011	7674425	EXPEDITED (15-DAY)	Y	HO	1000016938	74 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PEPTIC ULCER	LEXAPRO	S	ORAL	15 MG (15 MG,1 IN 1 D), ORAL		
MELAENA	AMLODIPINE	C				
GASTROINTESTINAL HAEMORRHAGE	ASPIRIN	C				
	ZOTON (LANSOPRAZOLE) (TABLETS) (LANSOPRFAZOLE)	C				
	VIT B12 (CYANOCOBALAMIN) (TABLETS) (CYANOCOBALAMIN)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Apr-2011	7905366	EXPEDITED (15-DAY)	N	OT,RI	1000019459	46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TOURETTE'S DISORDER	LEXAPRO	S	ORAL	1.25 MG (1.25 MG,1 IN 1 D),ORAL		
RESTLESS LEGS SYNDROME	HYZAAR (HYDROCHLOROTHIAZIDE, LOSARTAN) (HYDROCHLOROTHIAZIDE, LOSARTAN)	C				
ANXIETY						
ARTHRALGIA						
ASTHENIA						
BUTTERFLY RASH						
CERVICOBRACHIAL SYNDROME						
DEPRESSION						
DISTURBANCE IN ATTENTION						
DRUG DOSE OMISSION						
DYSKINESIA						
FALL						
FEELING ABNORMAL						
GAIT DISTURBANCE						
HEADACHE						
HYPERSOMNIA						
INSOMNIA						
NAIL DISORDER						
NECK PAIN						
PAIN IN EXTREMITY						
PARAESTHESIA						
POSTURE ABNORMAL						
PSORIASIS						
TINNITUS						
TREMOR						
VISUAL IMPAIRMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Apr-2011	7931493	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2011-01128	82 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC DISORDER	METOPROLOL TARTRATE	S		50MG-		
	LIPITOR	S		20MG-		
	CARDIZEM LA	S				
	LEXAPRO	S		10MG-		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Apr-2011	7898020	NON-EXPEDITED	N		US-ASTRAZENECA-2010SE 46008		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MIGRAINE	ATENOLOL	S				ZENECA
	LEXAPRO	S				
	TOPAMAX	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Apr-2011	7759841	EXPEDITED (15-DAY)	Y	OT,RI	1000017769	41 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MYALGIA	LEXAPRO	S		10 MG (10 MG,1 IN 1 D)		
TREMOR	LEXAPRO	S		5 MG (5 MG, 1 IN 1 D)		
FATIGUE						
FEELING ABNORMAL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Apr-2011	7934544	EXPEDITED (15-DAY)	Y	HO	1000020067	66 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPONATRAEMIA	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
UNRESPONSIVE TO STIMULI	XANAX (ALPRAZOLAM) (TABLETS) (ALPRAZOLAM)	C				
CONVULSION	NORTEM (TEMAZEPAM) (TABLETS) (TEMAZEPAM)	C				
COMMUNICATION DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Apr-2011	7354086	EXPEDITED (15-DAY)	Y	OT,RI	1000012683	37 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPERMATOGENESIS ABNORMAL	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
	LEXAPRO	S	ORAL	ORAL		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Apr-2011	7379193	EXPEDITED (15-DAY)	Y	CA,OT	1000013413	< 1 DAY	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TALIPES	LEXAPRO	S	TRANSPLACENTAL	20 MG (20 MG, 1 IN 1 D), TRANSPLACENTAL)		
NERVOUS SYSTEM DISORDER	SEROQUEL	S	TRANSPLACENTAL	200 MG (100 MG, 2 IN 1 D), TRANSPLACENTAL		
Maternal drugs affecting foetus	AFFEX (FLUOXETINE) (CAPSULES) (FLUOXETINE)	C				
POOR SUCKING REFLEX	RANITIDINE	C				
FLOPPY INFANT	AMOXICILLIN	C				
HYPERTONIA NEONATAL	AUGMENTIN (AUGMENTIN) (AUGMENTIN)	C				
HYPOTONIA NEONATAL	CYTAMEN (CYANOCOBALAMIN) (INJECTION) (CYANOCOBALAMIN)	C				
	GALFER (FERROUS FUMARATE) (FERROUS FUMARATE)	C				
	SOLPADOL (PARACETAMOL, CODEINE PHOSPHATE) (PARACETAMOL, CODEINE PHOSPHATE)	C				
	DIFENE (DICLOFENAC SODIUM) (DICLOFENAC SODIUM)	C				
	ZIMOVANE (ZOPICLONE) (TABLETS) (ZOPICLONE)	C				
	BUSCOPAN (HYOSCINE BUTYLBROMIDE) (TABLETS) (HYOSCINE BUTYLBROMIDE)	C				
	FASTUM (KETOPEROFEN) (GEL) (KETOPEROFEN)	C				
	GERTAC (RANITIDINE) (RANITIDINE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Apr-2011	7903521	NON-EXPEDITED	N		US-PFIZER INC-2011082157		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	PRISTIQ EXTENDED RELEASE	S		UNK, 1 x/day	2 DAY	PFIZER
HEADACHE	ZOLOFT	S		UNK		PFIZER
DRUG INTOLERANCE	LEXAPRO	S		UNK		
AGITATION	CELEXA	S		UNK		
ERECTILE DYSFUNCTION	ABILIFY	C		2 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Apr-2011	7909495	NON-EXPEDITED	N		US-ASTRAZENECA-2010SE 10297	67 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	TOPROL XL	S	ORAL			
OEDEMA PERIPHERAL	SYNTHROID	C				
	PREVACID	C				
	ALDACTONE	C				
	DEMADEX	C				
	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Apr-2011	7941597	EXPEDITED (15-DAY)	Y	OT,RI	1000020146	44 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
POLYNEUROPATHY	LEXAPRO	S	ORAL	(10 MG),ORAL, TEMPORARILY DOSE REDUCTION, ORAL		
	LEXAPRO	S	ORAL	ORAL		
	FLUTICASONE PROPIONATE (FLUTICASONE PROPIONATE) (FLUTICASONE PROPIONATE)	C				
	MONTELUKAST	C				
	PANTOZOL	C				
	AERIUS (DESLORATADINE) (TABLETS) (DESLORATADINE)	C				
	SPIRIVA (TIOTROPIUM BROMIDE) (TIOTROPIUM BROMIDE)	C				
	SYMBICORT(BUDESONIDE, FORMOTEROL FUMARATE) (BUDESONIDE, FORMOTEROL FUMARATE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Apr-2011	7944593	EXPEDITED (15-DAY)	N	CA	1000020152	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal drugs affecting foetus	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
CONGENITAL PULMONARY ARTERY ANOMALY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Apr-2011	7816534	EXPEDITED (15-DAY)	Y	HO,OT,RI	1000018510	82 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	LEXAPRO	S	ORAL	TABLETS (10 MG,1 IN 1 D),ORAL		
PNEUMONIA	LISINOPRIL	C				
GASTRIC HAEMORRHAGE	ZETIA	C				
RENAL FAILURE CHRONIC	THYROID META MAX (THYROID META MAX) (THYROID META MAX)	C				
FALL	COREG CR (CARVEDILOL) (CARVEDILOL)	C				
ASTHENIA	AVALIDE (IRBESARTAN, HYDROCHLOROTHIAZIDE) (IRBESARTAN, HYDROCHLOROTHIAZIDE)	C				
ANAEMIA	PROTONIX	C				
NAUSEA	REQUIP (ROPINIROLE HYDROCHLORIDE) (ROPINIROLE HYDROCHLORIDE)	C				
VOMITING	ROZEREM (RAMELTEON) (RAMELTEON)	C				
AGGRESSION	WELLBUTRIN XL (BUPROPION HYDROCHLORIDE) (BUPROPION HYDROCHLORIDE)	C				
CONFUSIONAL STATE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Apr-2011	7840783	EXPEDITED (15-DAY)	Y	OT	US-ENDO PHARMACEUTICALS INC.-HCTZ20110002	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GRAND MAL CONVULSION	HYDROCHLOROTHIAZIDE	S	ORAL			
HYPONATRAEMIA	LEXAPRO	S	ORAL			
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Apr-2011	7938570	DIRECT	N			29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COLITIS ULCERATIVE TREATMENT FAILURE	LEXAPRO	S	ORAL	20MG 1X PER DAY PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Apr-2011	7996286	NON-EXPEDITED	Y	HO	US-JNJFOC-20101005437	54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INTENTIONAL OVERDOSE	TYLENOL	S	ORAL	ORAL		
	LEXAPRO	S		20 MG, 1 IN 1 DAY		
	STUDY MEDICATION (INVESTIGATIONAL DRUG)	C				
	PREDNISONE	C				
	ACYCLOVIR	C				
	LISINOPRIL (LISINOPRIL)	C				
	NEXIUM	C				
	ATIVAN	C				
	ATENOLOL (ATENOLOL)	C				
	LIPITOR	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-May-2011	7924289	NON-EXPEDITED	N		US-PFIZER INC-2011090956	41 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	XANAX	S	ORAL	0.5 mg daily as needed		PFIZER
INSOMNIA	LEXAPRO	S	ORAL	10 mg, 1x/day		
DRUG INEFFECTIVE	LEXAPRO	S				
THERAPEUTIC RESPONSE UNEXPECTED	SYNTHROID	C		UNK		
	IMITREX	C		as required		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-May-2011	7951382	EXPEDITED (15-DAY)	N	OT,RI	1000020380	66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CATARACT	LEXAPRO	S	ORAL	10 MG (10 MG,L IN 1 D),0RAL		
GLAUCOMA	ASPIRIN (ACETYLSALICYLIC ACID) (81 MILLIGRAM, TABLETS) (ACETYLSALICYLIC ACID)	C				
	COQ10 (UBIDECARENONE) (UBIDE,CARENONE)	C				
	FOLIC ACID (FOLIC ACID)(1 MILLIGRAM, TABLETS)(FOLIC ACID)	C				
	FISH OIL (FISH OIL)(FISH OIL)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-May-2011	7944446	EXPEDITED (15-DAY)	Y	OT,RI	1000020240	40 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S		10 MG (10 MG,1 IN 1 D)		
PERSONALITY CHANGE	ESCITALOPRAM OXALATE	S				
AGGRESSION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D) ; 20 MG (20 MG,1 IN 1 D),ORAL		
THINKING ABNORMAL	SIMVASTATIN (SIMVASTATIN, SIMVASTATIN) (SIMVASTATIN, SIMVASTATIN)	C				
	CASSIA (CINNAMOMUM VERUM) (CINNAMOMUM VERUM)	C				
	PANADOL (PARACETAOL) (PARACETAMOL)	C				
	PERSAIC (PERSAIC) (PERSAIC)	C				
	NORVASC	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-May-2011	7959256	EXPEDITED (15-DAY)	Y	OT,RI	1000020574		Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-May-2011	7904963	EXPEDITED (15-DAY)	N	HO,OT,RI	S06-USA-01121-01	65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TENSION HEADACHE	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D), ORAL		
FATIGUE	VALIUM	C				
ASTHMA						
CHRONIC SINUSITIS						
DRUG INTOLERANCE						
Dry eye						
FEELING ABNORMAL						
HYPOMETABOLISM						
INSOMNIA						
LETHARGY						
LUNG CARCINOMA CELL TYPE UNSPECIFIED STAGE IV						
MALAISE						
PNEUMONIA						
RESTLESSNESS						
SOMNOLENCE						
TINNITUS						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-May-2011	7936915	EXPEDITED (15-DAY)	Y	HO	US-ALEXION-A201100045	88 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANAEMIA	SOLIRIS	S	INTRAVENOUS	600 mg, qwx4		ALEXION
HAEMORRHOIDS	SOLIRIS	S	INTRAVENOUS	900 mg, q2w		ALEXION
ASTHENIA	LEXAPRO	S	ORAL	UNK		
TINNITUS	TRANXENE T-TAB	C	ORAL	7.5 mg, tid prn		
RECTAL HAEMORRHAGE	FOLIC ACID	C	ORAL	1 mg, qd		
	CENTRUM / 00554501/	C	ORAL	UNK		
	LIPITOR	C	ORAL	40 mg, qd		
	ARIMIDEX	C	ORAL	1 mg, qd		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-May-2011	7951869	DIRECT	N	OT		32 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BRAIN INJURY	LEXAPRO	S	ORAL	ONE PER DAY PO 2 OR 3 WEEKS TWICE		
DISTURBANCE IN ATTENTION						
EUPHORIC MOOD						
FATIGUE						
MUSCLE TWITCHING						
SERUM SEROTONIN INCREASED						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-May-2011	7960586	EXPEDITED (15-DAY)	Y	HO,OT	1000020424	33 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MENTAL STATUS CHANGES	LEXAPRO	S	ORAL	(ONCE),ORAL		
AGGRESSION	LITHIUM CARBONATE	S	ORAL	(ONCE),ORAL		
SUICIDE ATTEMPT	ALCOHOL (ETHANOL)	S				
ELECTROCARDIOGRAM QT PROLONGED						
Intentional overdose						
LETHARGY						
SINUS BRADYCARDIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-May-2011	7964232	EXPEDITED (15-DAY)	N	HO	1000020702		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus						
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-May-2011	7964928	EXPEDITED (15-DAY)	N	OT,RI	1000020689		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus						
NEONATAL RESPIRATORY DISTRESS SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-May-2011	7964948	EXPEDITED (15-DAY)	N	CA	1000020694	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
EXOMPHALOS						
HERNIA						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-May-2011	7954525	DIRECT	Y	OT		20 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MYDRIASIS	CYMBALTA	S	ORAL	1 TAB 30 MG 1 TAB QHS PO		
	LEXAPRO	S	ORAL	1/2 TAB 10 MG -5 MG- 1/2 TAB QHS PO		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-May-2011	7955307	DIRECT	N	HO		57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANIC ATTACK	LEXAPRO	S	ORAL	5 MG TO BE INCREASED TO 10 MG 1 PER DAY PO		
BLOOD PRESSURE INCREASED						
HEART RATE INCREASED						
PSYCHOTIC DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-May-2011	7943934	NON-EXPEDITED	N		US-PFIZER INC-2010086429	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERHIDROSIS	CELEBREX	S	ORAL	UNK, 1x/day		PFIZER
HOT FLUSH	LEXAPRO	S	ORAL	10 mg, 1x/day		
DECREASED APPETITE	ZOLPIDEM	S	ORAL	10 mg, 1x/day		
HEADACHE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-May-2011	7971165	EXPEDITED (15-DAY)	N	OT	1000020724	32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
IMPAIRED DRIVING ABILITY	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
SEDATION	NORCO (VICODIN) (VICODIN)	C				
SOMNOLENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-May-2011	7675654	EXPEDITED (15-DAY)	N	HO,OT	PHHY2010BR75692		Male	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CEREBROVASCULAR ACCIDENT	DIOVAN HCT	S		320 mg valsartan /25mg hydrochlorothiazide		NOVARTIS
SHOCK	LEXAPRO	S		10 mg, UNK		
DEPRESSION	TRILEPTAL	C		600 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-May-2011	7960362	DIRECT	Y	OT		13 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG QD PO		
DISEASE RECURRENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-May-2011	7660983	EXPEDITED (15-DAY)	N	OT	US-RB-016370-10	36 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUBSTANCE ABUSE	SUBOXONE	S	SUBLINGUAL			RECKITT BENCKISER
SELF-INJURIOUS IDEATION	SUBOXONE	S	SUBLINGUAL	Sublingual Film		RECKITT BENCKISER
INSOMNIA	LEXAPRO	S	ORAL	Dosing information unknown		
DRUG DEPENDENCE	ABILIFY	C	UNKNOWN			
OVERDOSE	METFORMIN HYDROCHLORIDE	C	UNKNOWN	Dosing information unknown		
DIABETES MELLITUS						
DRUG WITHDRAWAL SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-May-2011	7975243	EXPEDITED (15-DAY)	Y	OT,RI	1000020817	35 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MOUTH ULCERATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL; 15 MG (15 MG, 1 IN 1 D), ORAL		
BLOOD CALCIUM DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-May-2011	7976222	EXPEDITED (15-DAY)	Y	OT	2011SP020484	9 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGGRESSION	NASONEX	S	INHALATION	INH		
	ASMANEX	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-May-2011	7865627	EXPEDITED (15-DAY)	Y	HO,OT	1000018954	31 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CYCLIC NEUTROPENIA	LEXAPRO	S	ORAL	ORAL		
	DIANETTE (CYPROTERONE ACETATE, ETHINYLESTRADIOL) (CYPROTERONE ACETATE, ETHINYLESTRADIOL)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-May-2011	7891489	EXPEDITED (15-DAY)	Y	HO,DS,LT,OT	AU-PFIZER INC-2011068790	44 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RENAL FAILURE ACUTE	PRISTIQ EXTENDED RELEASE	S	ORAL	50 mg, 1x/day	16 DAY	PFIZER
	LEXAPRO	S	ORAL	20 mg, UNK	46 DAY	
	IRBESARTAN & HYDROCHLOROTHIAZIDE	C	ORAL	12.5 mg/150mg, 1x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-May-2011	7997917	NON-EXPEDITED	N	OT	DSA_44810_2011	47 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	APLENZIN	S	ORAL	(348 MG QD ORAL)		
TREMOR	LEXAPRO	S	ORAL	(40 MG QD ORAL)		
TINNITUS	TRAZODONE HYDROCHLORIDE	C				
DISTURBANCE IN ATTENTION	OXYCODONE HYDROCHLORIDE	C				
URINARY TRACT INFECTION	XANAX	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2011	7872047	EXPEDITED (15-DAY)	N	OT	BR-PFIZER INC-BR-WYE-H15150010	44 YR	Female	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FLUID RETENTION	PRISTIQ EXTENDED RELEASE	S	ORAL	50 mg, 1x/day		PFIZER
WEIGHT INCREASED	PRISTIQ EXTENDED RELEASE	S				PFIZER
SWELLING	LEXAPRO	S		10 mg, 1x/day	666 DAY	
BODY MASS INDEX INCREASED	EUTHYROX	C	ORAL	100 ug, 1x/day		
WEIGHT LOSS POOR	RABEPRAZOLE SODIUM	C		20 mg, 1x/day	91 DAY	
WEIGHT FLUCTUATION	CELLULASE\DEHYDROCHOLIC ACID\METOCLOPRAMIDE \PANCREATIN\PEPSIN	C		1 DF, 1x/day	30 DAY	
WEIGHT DECREASED	CELLULASE\DEHYDROCHOLIC ACID\METOCLOPRAMIDE \PANCREATIN\PEPSIN	C				
	PANTOPRAZOLE	C		40 mg, 1x/day	91 DAY	
	LORAZEPAM	C		1 mg, weekly		
	FLUCONAZOLE	C		150 mg, 1x/day		
	CELEBREX	C		200 mg, occasionally		
	LEVOCETIRIZINE	C		1 DF, 1x/day	15 DAY	
	DICLOFENAC DIETHYLAMINE	C		75 mg, 1x/day	7 DAY	

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2011	7977416	DIRECT	N	DE		68 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	10 MG 2 PER DAY ORAL		FOREST
DRUG INEFFECTIVE	LEVAQUIN	S	ORAL	500MG 1 PER DAY ORAL		JANSSEN
PRODUCT SUBSTITUTION ISSUE	CIPROFLOXACIN	S				COBALT
INSOMNIA	SULFAMETHOXAZOLE \TRIMETHOPRIM	C				
GUN SHOT WOUND	DOXYCYCLINE	C				
COMPLETED SUICIDE	LEVAQUIN	C				
	ZOLPIDEM	C				
	FLOMAX	C				
	ACTOS	C				
	AMLODIPINE	C				
	BENAZEPRIL HYDROCHLORIDE	C				
	CRESTOR	C				
	METFORMIN HYDROCHLORIDE	C				
	DOCUSATE SODIUM	C				
	IBUPROFEN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2011	7989315	EXPEDITED (15-DAY)	Y	OT,RI	1000020974	41 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LEXAPRO	S	ORAL	ORAL		
DEPRESSION	FENTANYL	S	TRANSDERMAL	TRANSDERMAL		
CRYING	OXYCODONE (OXYCODONE)	C				
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-May-2011	7963155	NON-EXPEDITED	N		US-MYLANLABS-2010S1011986	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERHIDROSIS	ZOLPIDEM TARTRATE	S	ORAL			
HOT FLUSH	LEXAPRO	S	ORAL			ALPHAPHARM
DECREASED APPETITE	CELEBREX	S				
HEADACHE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2011	7985669	DIRECT	N	CA,RI		< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal drugs affecting foetus	LEXAPRO	S				
DEAFNESS CONGENITAL						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2011	8029073	NON-EXPEDITED	Y	OT	US-001845	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ELECTROCARDIOGRAM QT PROLONGED	TRAZODONE HYDROCHLORIDE	S	ORAL	(ORAL)		
	TELAVANCIN HYDROCHLORIDE	S	INTRAVENOUS	(10 MG/KG, TOTAL DOSE INTRAVENOUS (NOT OTHERWISE SPECIFIED))		
	LEXAPRO	S	ORAL	(ORAL)		
	METOCLOPRAMIDE	C				
	WARFARIN SODIUM	C				
	NOVOLIN R	C				
	HYDROMORPHONE HYDROCHLORIDE	C				
	METOPROLOL TARTRATE	C				
	LISINOPRIL	C				
	SITAGLIPTIN	C				
	IMDUR	C				
	LASIX	C				
	CILOSTAZOL	C				
	COLECALCIFEROL	C				
	CALCIUM CITRATE	C				
	OMEPRAZOLE	C				
	ZOLPIDEM	C				
	LIPITOR	C				
	FENTANYL	C				
	LANTUS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2011	7986371	DIRECT	N	LT		53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EMOTIONAL DISORDER	LEXAPRO	S				
ANXIETY						
DEPRESSED MOOD						
SUICIDAL BEHAVIOUR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2011	7996116	EXPEDITED (15-DAY)	Y	HO	1000021229	46 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOTENSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 I N 1 D), ORAL		
FALL	QUETIAPINE FUMARATE	S		100 MG (100 MG, 1 IN 1 D)		
DRUG INTERACTION	IRBESARTAN & HYDROCHLOROTHIAZIDE	S		1 DF (1 DOSAGE FORMS, 1 I N1 D)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2011	7997197	EXPEDITED (15-DAY)	N	OT,RI	1000021166		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEMIPLEGIA	LEXAPRO	S				
CONVULSION						
HEART RATE DECREASED						
MIGRAINE						
SPEECH DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jun-2011	7989493	DIRECT	Y			65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	LEXAPRO	S	ORAL	10 QD PO (DATES OF USE: UNKNOWN, SEVERAL MONTHS)		
INSOMNIA	VENLAFAXINE	S	ORAL	37.5 MG BID PO (DATES OF USE: UNKNOWN, SEVERAL MONTHS)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jun-2011	7976491	NON-EXPEDITED	N		US-BAYER-201028563NA	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERSENSITIVITY	AVELOX	S	ORAL	400 mg, QD	1 DAY	BAYER
SWELLING FACE	IBUPROFEN	C		UNK UNK, PRN		BAYER
SWOLLEN TONGUE	LEXAPRO	S	ORAL	10 mg, QD		
	NICODERM CQ	S		UNK	1 DAY	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jun-2011	8006336	EXPEDITED (15-DAY)	N	DE	1000021283	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEART DISEASE CONGENITAL	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus	ZOLOFT	S	TRANSPLACENTAL	TRANSPLACENTAL		
AORTIC OCCLUSION						
CARDIAC VENTRICULAR DISORDER						
LEFT VENTRICULAR FAILURE						
OBSTRUCTION						
POST PROCEDURAL COMPLICATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jun-2011	7980181	NON-EXPEDITED	Y		US-PFIZER INC-2011121825	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING JITTERY	PRISTIQ EXTENDED RELEASE	S		50 mg		PFIZER
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jun-2011	7904077	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20110403801	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RESPIRATORY DISTRESS	TOPAMAX	S	TRANSPLACENTAL			
APNOEA	TOPAMAX	S	TRANSPLACENTAL	start date- 19-OCT		
METABOLIC ACIDOSIS	LEXAPRO	S	TRANSPLACENTAL	on therapy for 7 weeks		
HYPOTONIA	ELAVIL	S	TRANSPLACENTAL			
BRADYCARDIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jun-2011	7997433	DIRECT	Y			65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INSOMNIA	LEXAPRO	S	ORAL	10 QD PO		
FATIGUE	VENLAFAXINE HYDROCHLORIDE	S	ORAL	37.5MG BID PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jun-2011	8007717	EXPEDITED (15-DAY)	N	CA	1000021289	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VASCULAR ANOMALY	LEXAPRO	S	TRANSPLACENTAL	20 MG (20 MG,1 IN 1 D),TRANSPLACENTAL		

Maternal drugs affecting foetus

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jun-2011	8009110	EXPEDITED (15-DAY)	Y	OT,RI	1000021443	14 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BREAST PAIN	LEXAPRO	S				
CONTUSION						
PETECHIAE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jun-2011	7869905	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20110307442	82 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION	TYLENOL	S	ORAL			
OCCIPITAL NEURALGIA	TYLENOL	S	ORAL	1000mg 3-4 times day		
BLOOD PRESSURE INCREASED	LEXAPRO	S	ORAL			
INCORRECT DRUG ADMINISTRATION DURATION	LEXAPRO	S	ORAL	8-10 years		
DECREASED APPETITE	METHYLPREDNISOLONE	C	ORAL			
HEADACHE	ATENOLOL	C	ORAL			
	LEVOTHYROX	C	ORAL			
	VALSARTAN W/ HYDROCHLOROTHIAZIDE	C	ORAL	81mg/25mg, 8-10 years		
	OCUVITE NOS	C	ORAL	6-7 years		
	VITAMINS	C	ORAL			
	BAYER ASPIRIN	C	ORAL			
	LOVAZA	C	ORAL			
	VITAMIN D	C	ORAL			
	CALCIUM CARBONATE	C	ORAL			
	OMEPRAZOLE	C	ORAL			
	UBIDECARENONE	C	ORAL			
	FISH OIL	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jun-2011	8009709	EXPEDITED (15-DAY)	Y	OT,RI	1000021495	77 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	LEXAPRO	S				
BLOOD CREATININE INCREASED	PRISTIQ EXTENDED RELEASE	S				
BLOOD UREA INCREASED	CARTIA (DILTIAZEM HYDROCHLORIDE) (TABLETS) (DILTIAZEM HYDROCHLORIDE)	C				
GLOMERULAR FILTRATION RATE DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jun-2011	7963584	EXPEDITED (15-DAY)	N	OT,RI	1000020645		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D), ORAL		
	CARBAMAZEPINE	C				
	PROPRANOLOL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jun-2011	7987761	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-15810377		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	TRAZODONE HYDROCHLORIDE	S		half a bottle		APOTHECON
OVERDOSE	ABILIFY	S		for a while but not for two days		
MULTIPLE SCLEROSIS	LEXAPRO	S		half a bottle		
	COPAXONE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jun-2011	7794508	EXPEDITED (15-DAY)	Y	HO	1000017750	43 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WITHDRAWAL SYNDROME	LEXAPRO	S		15 MG (15 MG, 1 IN 1 D) 10 MG (10 MG, 1 IN 1 D) 5 MG (5 MG, 1 IN 1 D)		
AKATHISIA	LEXAPRO	S		5 MG (5 MG, 1 IN 1 D)		
RESTLESSNESS	RISPERIDONE (RISPERIDONE) (TABLETS) (RISPERIDONE)	C				
	SEROQUEL (QUETIAPINE FUMARATE) (QUETIAPINE FUMARATE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jun-2011	7992956	EXPEDITED (15-DAY)	N	DE	US-ABBOTT-11P-163-0731364-00	4 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal exposure during pregnancy	LEXAPRO	S	TRANSPLACENTAL			
LEFT VENTRICULAR FAILURE	ZOLOFT	S	TRANSPLACENTAL			
CONGENITAL CARDIOVASCULAR ANOMALY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jun-2011	8014551	EXPEDITED (15-DAY)	Y	OT,RI	1000021543		Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jun-2011	8014698	EXPEDITED (15-DAY)	Y	DE	1000021538	48 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S		1 DF (1 DOSAGE FORMS, 1 IN 1 D)		
ABNORMAL BEHAVIOUR	CODEINE\IBUPROFEN	S				
PSYCHOTIC DISORDER	ACETAMINOPHEN\CODEINE PHOSPHATE	S				
BIPOLAR DISORDER	ZOLPIDEM TARTRATE	S		10 MG (10 MG, 1 IN 1 D)		
ABNORMAL SLEEP-RELATED EVENT						
DROWNING						
HALLUCINATION, AUDITORY						
SOMNAMBULISM						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jun-2011	7993930	NON-EXPEDITED	Y		US-PFIZER INC-2011131333		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LIVER FUNCTION TEST ABNORMAL	CHANTIX	S		UNK		PFIZER
	LEXAPRO	S		UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jun-2011	8007556	DIRECT	N			49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LIBIDO DECREASED	LEXAPRO	S	ORAL	1 TABLET DAILY PO		
AMNESIA						
ASTHENIA						
CONFUSIONAL STATE						
Coordination abnormal						
DEPRESSION						
DIZZINESS						
EUPHORIC MOOD						
FATIGUE						
HEART RATE INCREASED						
HYPERHIDROSIS						
IMPULSIVE BEHAVIOUR						
INSOMNIA						
SOMNOLENCE						
VISUAL IMPAIRMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jun-2011	8007635	DIRECT		OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LIBIDO DECREASED	LEXAPRO	S				
FEMALE ORGASMIC DISORDER	ZOLOFT	S				
SEXUAL DYSFUNCTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jun-2011	8017203	EXPEDITED (15-DAY)	N	CA	1000021589	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CRANIOSYNOSTOSIS	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
CONGENITAL ANOMALY						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jun-2011	8348736	EXPEDITED (15-DAY)	N	DE,CA	1000021572	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONGENITAL TRICUSPID VALVE ATRESIA	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
ATRIAL SEPTAL DEFECT						
CONGENITAL ANOMALY						
HYPOPLASTIC RIGHT HEART SYNDROME						
Maternal drugs affecting foetus						
PULMONARY VALVE STENOSIS						
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Jun-2011	7893206	EXPEDITED (15-DAY)	Y	HO,OT,RI	1000019259		Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LEXAPRO	S		10 MG (10 MG,1 IN 1 D)		
TREMOR	OMEPRAZOLE	S				
DYSPHAGIA	AMANTADINE (AMANTADINE) (AMANTADINE)	C				
CONDITION AGGRAVATED						
NEUROLEPTIC MALIGNANT SYNDROME						
SEROTONIN SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Jun-2011	7995648	EXPEDITED (15-DAY)	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-15705049	30 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FAILURE TO THRIVE	ABILIFY	S	TRANSPLACENTAL	The baby's mother was receiving aripiprazole 2.5 mg daily and was breast feeding the baby.		
MENSTRUAL DISORDER	ABILIFY	S	TRANSPLACENTAL	The baby's mother was receiving aripiprazole 2.5 mg daily and was breast feeding the baby.		
GASTROOESOPHAGEAL REFLUX DISEASE	LEXAPRO	S	TRANSPLACENTAL	The baby's mother was on therapy with escitalopram oxalate and was breast feeding the baby.		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jun-2011	8014319	DIRECT	N	LT,RI		29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S	ORAL	VARIED 10 MG TO 20MG DAILY PO		FOREST
BLOOD CHOLESTEROL INCREASED						
DECREASED ACTIVITY						
DISCOMFORT						
DYSPNOEA						
HYPERPHAGIA						
INCREASED APPETITE						
PRODUCT QUALITY ISSUE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jun-2011	8014493	DIRECT	N	OT		31 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABORTION SPONTANEOUS	LEXAPRO	S	ORAL	10MG DAILY PO		
FEELING ABNORMAL						
MATERNAL EXPOSURE DURING PREGNANCY						
PARAESTHESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2011	8001511	EXPEDITED (15-DAY)	N	OT	US-RANBAXY-2011US-44588		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AMNESIA	LORAZEPAM	S	ORAL	1 mg tablet in evening		RANBAXY
DRUG WITHDRAWAL SYNDROME	LORAZEPAM	S	ORAL	0.5 mg tablet in morning		RANBAXY
	TEGRETOL	S	UNKNOWN	600 mg, UNK		
	LITHIUM	S	UNKNOWN	750 mg, UNK		
	LEXAPRO	S	UNKNOWN	10 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2011	8018445	DIRECT	N	OT		51 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PARAESTHESIA	LEXAPRO	S	ORAL	20 MG 1.5 DAILY ORAL		FOREST
DRUG DEPENDENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2011	8027929	EXPEDITED (15-DAY)	N	OT,RI	1000021585	47 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOCAPNIA	LEXAPRO	S	ORAL	ORAL		
WEIGHT INCREASED	VENLAFAXINE HYDROCHLORIDE	S	ORAL	37.5 MG (37.5 MG, 1 IN 1 D), ORAL; 75 MG (75 MG, 1 IN 1 D), ORAL		
SEXUAL DYSFUNCTION	PROZAC	S	ORAL	(1 IN 1 D), ORAL		
FATIGUE	TRAZODONE (TRAZODONE) (50 MILLIGRAM, TABLETS) (TRAZODONE)	C				
	Z-DEX 12D (DEXTROMETHORPHAN, CHLORPHENIRAMINE, PHENYLEPHRINE) (DEXTROMETHORPHAN, CHLORPHENIRAMINE, P	C				
	SOMINEX (METHAPYRILENE HYDROCHLORIDE, SALICYLAMIDE, SCOPOLAMINE AMINOXIDE HYDROBROMIDE) (METHAPYRILE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2011	8027932	EXPEDITED (15-DAY)	N	OT,RI	1000021622	25 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GRAND MAL CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
PETIT MAL EPILEPSY	ZYRTEC	C				
LOSS OF CONSCIOUSNESS						
WEIGHT INCREASED						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jun-2011	8003995	NON-EXPEDITED	Y	OT	US-PFIZER INC-2011133845		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOMANIA	ZOLOFT	S		UNK		PFIZER
	LEXAPRO	S		UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jun-2011	7974258	EXPEDITED (15-DAY)		HO,OT	US-ASTRAZENECA-2011SE32305	82 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cervical vertebral fracture	CRESTOR	S	ORAL			
BLADDER NECK SUSPENSION	LEXAPRO	S	UNKNOWN			
ASTHENIA						
CATARACT OPERATION						
CEREBROVASCULAR ACCIDENT						
CONFUSIONAL STATE						
CORONARY ARTERY DISEASE						
DEHYDRATION						
DEMENTIA ALZHEIMER'S TYPE						
EJECTION FRACTION DECREASED						
FALL						
HYPERSOMNIA						
INCONTINENCE						
LOSS OF CONSCIOUSNESS						
PNEUMONIA						
PRESYNCOPE						
RADIOISOTOPE SCAN						
SPINAL FUSION SURGERY						
SUICIDAL IDEATION						
SYNCOPE						
URINARY TRACT INFECTION						
VENTRICULAR TACHYCARDIA						
VOMITING						
WEIGHT DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jun-2011	8010305	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2011136800		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME	GEODON	S		60 mg, UNK		PFIZER
ANXIETY	LEXAPRO	S		UNK		
PANIC ATTACK						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2011	8023459	DIRECT	N	LT,OT		56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEAT EXHAUSTION	LEXAPRO	S	ORAL	10MG DAILY PO	2 YR	
HEAT STROKE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2011	8036210	EXPEDITED (15-DAY)	Y	HO	1000021734		Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANCREATITIS ACUTE	LEXAPRO	S				
LEUKOCYTOSIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2011	8014342	NON-EXPEDITED	N		A0859251A		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LIBIDO DECREASED	ZYBAN	S				GLAXOSMITHKLINE
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2011	8024544	DIRECT	N	DS		46 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TINNITUS	LEXAPRO	S	ORAL	2.5 MG 3 TIMES ORAL		
EAR DISCOMFORT						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jun-2011	7749643	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010182248	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
POST-TRAUMATIC STRESS DISORDER	EFFEXOR XR	S	ORAL	75 mg, daily		PFIZER
SUFFOCATION FEELING	EFFEXOR XR	S	ORAL	120 mg, UNK		PFIZER
ALTERED STATE OF CONSCIOUSNESS	EFFEXOR XR	S	ORAL	150 mg, daily		PFIZER
NERVOUS SYSTEM DISORDER	EFFEXOR XR	S		UNK		PFIZER
MENTAL DISORDER	PROZAC	S	ORAL	20 mg, UNK		
ANXIETY	VALIUM	S	ORAL	10 mg, 1x/day		
AGITATION	ZYPREXA	S	ORAL	1 mg, 1x/day		
DRUG INTOLERANCE	ZYPREXA	S		UNK		
SEDATION	LEXAPRO	S	ORAL	UNK		
INSOMNIA	LEXAPRO	S		UNK		
DYSPHAGIA	CALCIUM	C	ORAL	UNK		
DRUG INEFFECTIVE	MULTIVITAMINS	C	ORAL	UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jul-2011	8031408	DIRECT	Y	DE		3 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal drugs affecting foetus	LEXAPRO	S	ORAL	PO		FOREST
VACUUM EXTRACTOR DELIVERY	AMPICILLIN SODIUM	C				
FOETAL HYPOKINESIA	CEFTOTAXIME	C				
METABOLIC ACIDOSIS	LASIX	C				
HYPOPERFUSION	GENTAMICIN	C				
HEPATIC STEATOSIS	POTASSIUM CHLORIDE	C				
DEATH NEONATAL	NA BICARB	C				
CARDIO-RESPIRATORY ARREST NEONATAL	MIDAZOLAM	C				
CARDIAC DISORDER	MORPHINE	C				
	DOBUTAMINE HYDROCHLORIDE	C				
	DOPAMINE	C				
	EPINEPHRINE	C				
	MILRINONE	C				
	TPN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jul-2011	7947888	EXPEDITED (15-DAY)	Y	HO,OT	US-JNJFOC-20110506107		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Apnoea neonatal	TOPAMAX	S	TRANSPLACENTAL			
HYPOTONIA	TOPAMAX	S	TRANSPLACENTAL			
METABOLIC ACIDOSIS	LEXAPRO	S	TRANSPLACENTAL			
APGAR SCORE LOW	OMEPRAZOLE	S	TRANSPLACENTAL			
BRADYCARDIA	AMPICILLIN SODIUM	S	TRANSPLACENTAL			
	GENTAMICIN	S	TRANSPLACENTAL			
	CLINDAMYCIN	S	TRANSPLACENTAL			
	ELAVIL	C	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jul-2011	8041032	EXPEDITED (15-DAY)	N	HO	2011SP030151	47 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SOMNOLENCE	REMERON	S	ORAL	45 MG;QD;PO		
PANIC ATTACK	LEXAPRO	S		2.5 MG ; 5 MG		
ANXIETY	CYMBALTA	S				
FEELING ABNORMAL	ABILIFY	S				
	ALLOPURINOL	C				
	RAMIPRIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jul-2011	8730557	DIRECT	N	OT		45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash	LEXAPRO 10 FOREST LABORATORIES	S	ORAL			FOREST
Asthma						
Lymphadenopathy						
Urticaria						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jul-2011	8026162	NON-EXPEDITED	N		US-PFIZER INC-2011152599		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
URTICARIA	PRISTIQ EXTENDED RELEASE	S	ORAL	76 mg, daily	35 DAY	PFIZER
HYPERSENSITIVITY	LEXAPRO	S	ORAL	10 mg, daily		
HEADACHE	KLONOPIN	S	ORAL	UNK		
INTERVERTEBRAL DISC DISORDER	CALCIUM	C		1200 mg, daily		

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Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2011	8046971	DIRECT	N	OT		36 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	LEXAPRO	S	ORAL	20 MG LEXAPRO 1X DAILY ORAL TABLET		FOREST
IMPULSIVE BEHAVIOUR	NAPROXEN SODIUM	C				
MUSCLE TWITCHING	MAXCIDE	C				
WEIGHT INCREASED	CELEXA	C				
DEPERSONALISATION	THYROID HORMONE THERAPY	C				
GRANDIOSITY	TAHITI TRIM FEMALE HORMONE CREAM	C				
ACNE						
ALOPECIA						
DELUSION						
DRY MOUTH						
HAIR GROWTH ABNORMAL						
IMPRISONMENT						
IRRITABILITY						
KLEPTOMANIA						
MOOD ALTERED						
NAIL GROWTH ABNORMAL						
ONYCHOCLASIS						
SOMNOLENCE						
WEIGHT LOSS POOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2011	8042836	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2011-BP-17477BP	83 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	PRADAXA	S	ORAL	300 mg		BOEHRINGER INGELHEIM
	LEXAPRO	S	ORAL	10 mg		
	COREG	C	ORAL	25 mg		
	LISINOPRIL	C	ORAL	20 mg		
	LASIX	C	ORAL	40 mg		
	AMIODARONE	C	ORAL	200 mg		
	ASPIRIN	C	ORAL	81 mg		
	FOLIC ACID	C	ORAL	1 mg		
	XANAX	C	ORAL			
	FOSAMAX	C	ORAL			
	CALCIUM CARBONATE	C	ORAL	1000 mg		
	SYNTHROID	C	ORAL	75 mg		
	VITAMIN B12	C	INTRAMUSCULAR			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2011	8043958	NON-EXPEDITED	N		US-KINGPHARMUSA00001-K201000880	62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEVOXYL	S	ORAL	162 mcg, qd		KING
HYPERTHYROIDISM	LEVOXYL	S	ORAL	137 mcg, qd		KING
THYROXINE FREE INCREASED	LEVOXYL	S	ORAL	150 mcg, qd		KING
	LEXAPRO	S	ORAL	20 mg, qd		
	LIPITOR	C		UNK		
	ATENOLOL	C		UNK		
	AMBIEN	C		UNK		
	KLONOPIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2011	8044030	NON-EXPEDITED	N		US-KINGPHARMUSA00001-K201001061		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD GLUCOSE INCREASED	LEVOXYL	S	ORAL	125 mcg, UNK		KING
FATIGUE	LEXAPRO	S		10 mg, UNK		
	METFORMIN HYDROCHLORIDE	C				
	BYETTA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jul-2011	7995914	NON-EXPEDITED	N		US-PFIZER INC-2011131979	31 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MALAISE	EFFEXOR	S		UNK		PFIZER
DRUG INEFFECTIVE	EFFEXOR	S				PFIZER
Medication residue present	XANAX	S		0.5 mg, UNK		PFIZER
DIARRHOEA	XANAX	S		1 mg, 1x/day		PFIZER
NAUSEA	XANAX	S		2 mg, 2x/day		PFIZER
ANXIETY	LEXAPRO	S		UNK		
STRESS	LEXAPRO	S				
	PRILOSEC	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jul-2011	8060021	DIRECT		OT		29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD FOLLICLE STIMULATING HORMONE INCREASED	LEXAPRO	S	ORAL	20 MG QD PO		FOREST
PREMATURE MENOPAUSE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jul-2011	8051993	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15362122	56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RASH	COUMADIN	S				BRISTOL MYERS SQUIBB
	COUMADIN	S				BRISTOL MYERS SQUIBB
	LEXAPRO	S	ORAL	Tabs		
	PROTONIX	S	ORAL	tabs		
	MULTIVITAMINS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jul-2011	8071930	EXPEDITED (15-DAY)	Y	HO	1000022336	23 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
AFFECT LABILITY						
AGGRESSION						
COMPULSIVE SHOPPING						
LOGORRHOEA						
PSYCHOMOTOR HYPERACTIVITY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jul-2011	8059586	NON-EXPEDITED	Y	OT	US-PFIZER INC-2011170545	45 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	CHANTIX	S		UNK		PFIZER
HYPERHIDROSIS	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jul-2011	8060844	EXPEDITED (15-DAY)	N	HO,OT	BR-SANOFI-AVENTIS-2011SA047666		Male	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ISCHAEMIC STROKE	LANTUS	S	SUBCUTANEOUS			
HYPERCHOLESTEROLAEMIA	ACETYLSALICYLIC ACID	S				
BLOOD THYROID STIMULATING HORMONE INCREASED	METFORMIN HYDROCHLORIDE	S				
	LEXAPRO	S				
	THIAMINE HYDROCHLORIDE	S				
	LOSARTAN POTASSIUM	C				
	METOPROLOL SUCCINATE	C				
	HUMALOG	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Aug-2011	7826813	EXPEDITED (15-DAY)	N	HO,DS,OT	2010SP040550	36 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CEREBROVASCULAR ACCIDENT	NUVARING	S				
DEPRESSION	LEXAPRO	S				
POST-TRAUMATIC STRESS DISORDER	DILANTIN	S				
CONVULSION	ADVIL	C				
CHOLELITHIASIS	CANNABIS SATIVA SUBSP. INDICA TOP	C				
AMBLYOPIA						
AMENORRHOEA						
ARTERIOVENOUS MALFORMATION						
BACK PAIN						
BLOOD FOLLICLE STIMULATING HORMONE INCREASED						
BLOOD IRON DECREASED						
BRAIN MIDLINE SHIFT						
BRAIN OEDEMA						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CEREBRAL HAEMORRHAGE						
CEREBRAL INFARCTION						
CHOLECYSTITIS						
CYST						
DIARRHOEA						
DISORIENTATION						
DIZZINESS						
DRUG ERUPTION						
ENCEPHALOMALACIA						
EPILEPSY						
EYE LASER SURGERY						
FATIGUE						
GALLBLADDER DISORDER						
HETEROPHORIA						
HORMONE LEVEL ABNORMAL						
HOT FLUSH						
HYPERCOAGULATION						
HYPERHIDROSIS						
HYPERLIPIDAEMIA						
HYPOAESTHESIA						
HYPOVITAMINOSIS						
INSOMNIA						
INTRACRANIAL VENOUS SINUS THROMBOSIS						
JAW DISORDER						
LIBIDO DECREASED						
MENIERE'S DISEASE						
MENSTRUATION IRREGULAR						
MOUNTAIN SICKNESS ACUTE						
MUSCLE SPASMS						
MUSCLE TIGHTNESS						
NAUSEA						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NERVOUSNESS						
NIGHT SWEATS						
NO THERAPEUTIC RESPONSE						
OBSTRUCTION						
OLIGOMENORRHOEA						
PANIC REACTION						
PAROSMIA						
PREGNANCY TEST POSITIVE						
SCOTOMA						
SINUS CONGESTION						
STRESS						
TEMPOROMANDIBULAR JOINT SYNDROME						
TINNITUS						
TOXICITY TO VARIOUS AGENTS						
TRANSAMINASES INCREASED						
TRANSIENT ISCHAEMIC ATTACK						
TRANSVERSE SINUS THROMBOSIS						
URTICARIA						
VERTIGO						
VISUAL FIELD DEFECT						
VITAMIN D DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Aug-2011	8735273	DIRECT	N	OT		34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION, VISUAL	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Aug-2011	8730903	DIRECT	N	DS		34 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	LEXAPRO	S	ORAL	10MG ONCE DAILY		FOREST
AKATHISIA						
BONE DISORDER						
CEREBROVASCULAR ACCIDENT						
EMOTIONAL DISORDER						
FEELING ABNORMAL						
HOMICIDAL IDEATION						
INFLUENZA LIKE ILLNESS						
MANIA						
PANIC ATTACK						
PARAESTHESIA						
SUICIDAL IDEATION						
TINNITUS						
UNEVALUABLE EVENT						
VISUAL ACUITY REDUCED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Aug-2011	8052948	EXPEDITED (15-DAY)	N	OT	US-SANOFI-AVENTIS-2011SA046917	45 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HOMICIDE	ZOLPIDEM	S	ORAL			
ANGER	CITALOPRAM	S	UNKNOWN			
AMNESIA	DIPHENHYDRAMINE	S	UNKNOWN			
AGITATION	ACETONE	S	UNKNOWN			
	CAFFEINE CITRATE	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	XANAX	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Aug-2011	8091309	EXPEDITED (15-DAY)	N	OT,RI	1000022560	17 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PLATELET COUNT DECREASED	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Aug-2011	8079432	NON-EXPEDITED	N		US-PFIZER INC-2011179842	33 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MALAISE	ADVIL	S	ORAL	200 mg three to four tablets		PFIZER
NAUSEA	ADVIL	S	ORAL	UNK		PFIZER
HEADACHE	LEXAPRO	S		UNK		
ANXIETY	ALPRAZOLAM	C		2 mg, 2x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Aug-2011	8094682	EXPEDITED (15-DAY)	N	OT,RI	1000022669	25 YR	Male	CHN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HAEMATOCHEZIA	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL, 10 MG (10 MG, 1 IN 1 D), ORAL, 15 MG (15 MG, 1 IN 1 D), ORAL		
CONSTIPATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Aug-2011	8111198	EXPEDITED (15-DAY)	Y	OT,RI	1000022630		Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NEPHROLITHIASIS	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Aug-2011	8742829	DIRECT	Y			65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	LEXAPRO	S		One per day		
NAUSEA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Aug-2011	8088605	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2011181339	45 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANGER	XANAX	S		UNK		PFIZER
HOMICIDE	CITALOPRAM	S		UNK		
AMNESIA	ZOLPIDEM TARTRATE	S	ORAL	10 mg, UNK		
AGITATION	DIPHENHYDRAMINE	S		UNK		
DRUG LEVEL ABOVE THERAPEUTIC	ACETONE	S		UNK		
	CAFFEINE	S		UNK		
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Aug-2011	8048669	EXPEDITED (15-DAY)	N	HO	1000021874		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANIC ATTACK	VIIBRYD	S				
DYSPNOEA	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Aug-2011	8096990	DIRECT	N	OT		38 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONSTIPATION	LEXAPRO	S		1 DAILY		
MUSCLE SPASMS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Aug-2011	8108005	EXPEDITED (15-DAY)	N	OT	1000022824		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Aug-2011	8118144	EXPEDITED (15-DAY)	N	OT,RI	1000022248	45 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	LEXAPRO	S				
ANGER	AMBIEN	S	ORAL	10 MG PRN (10 MG,AS NEEDED),ORAL		
HOMICIDE	XANAX	S				
LOSS OF CONSCIOUSNESS	DIPHENHYDRAMINE HYDROCHLORIDE	C				
AMNESIA	ACETONE (ACETONIE) (ACETONE)	C				
IMPRISONMENT	CAFFEINE (CAFFEINE) (CAFFEINE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Aug-2011	8748927	DIRECT	N	OT		68 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	1 & 1/2 TABLETS, DAILY, PO		
ANHEDONIA						
DEPRESSED MOOD						
FEELING ABNORMAL						
FEELINGS OF WORTHLESSNESS						
HYPERSOMNIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Aug-2011	8014704	EXPEDITED (15-DAY)	Y	OT,RI	1000021540	61 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANAL HAEMORRHAGE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ECCHYMOSIS	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
	SPIRIVA (TIOTROPIUM BROMIDE) (TIOTROPIUM BROMIDE)	C				
	SIMVASTATINE (SIMVASTATIN) (TABLETS) (SIMVASTATIN)	C				
	SYMBICORT (BUDESONIE, FORMOTEROL FUMARATE) (BUDESONIDE, FORMOTEROL FUMARATE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Aug-2011	8112142	EXPEDITED (15-DAY)	N	OT	AUR-APL-2011-04656	45 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	CITALOPRAM HYDROBROMIDE	S				
ANGER	ZOLPIDEM	S	ORAL	(10 MG), ORAL		
HOMICIDE	XANAX	S				
AMNESIA	DIPHENHYDRAMINE HYDROCHLORIDE	S				
IMPRISONMENT	ACETONE	S	ORAL			
ANTIDEPRESSANT DRUG LEVEL ABOVE THERAPEUTIC	CAFFEINE	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Aug-2011	8099518	NON-EXPEDITED	N		US-PFIZER INC-2011190779	42 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG DOSE OMISSION	PRISTIQ EXTENDED RELEASE	S	ORAL	50 mg, daily		PFIZER
FEELING ABNORMAL	LEXAPRO	S	ORAL	20 mg, daily		
STRABISMUS						
VISION BLURRED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Aug-2011	8116421	EXPEDITED (15-DAY)	Y	OT,RI	1000022928	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LYMPHOCYTIC INFILTRATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DIARRHOEA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Aug-2011	8142733	EXPEDITED (15-DAY)	Y	HO,OT,RI	1000022847	72 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR EXTRASYSTOLES	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL 5 MG (5 MG, 1 IN 1 D), ORAL		
VENTRICULAR ARRHYTHMIA	NADOLOL	C				
VENTRICULAR TACHYCARDIA	CRESTOR	C				
CORONARY ARTERY DISEASE	ASPIRIN (ACETYLSALICYLIC ACID)	C				
	MICARDIS	C				
	JANUMET(SITAGLIPTIN, METFORMIN)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Aug-2011	8118554	EXPEDITED (15-DAY)	N	CA	1000022942	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal drugs affecting foetus	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
CONGENITAL ANOMALY						
HYDROCEPHALUS						
SPINA BIFIDA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Aug-2011	8120845	EXPEDITED (15-DAY)	N	CA	1000022949	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOPLASTIC LEFT HEART SYNDROME	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Aug-2011	8096345	EXPEDITED (15-DAY)	Y	HO	1000022646	71 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSPNOEA	LEXAPRO	S	ORAL	10 MG (10 MG, IN 1 D) ORAL		
INTERSTITIAL LUNG DISEASE	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
PULMONARY HYPERTENSION	PROMOCARD DURETTE (ISOSORBIDE MONONITRATE) (TABLETS)	C				
	ALBUTEROL	C				
	ACETYLSALICYLIC ACID	C				
	ESOMEPRAZOLE MAGNESIUM	C				
	OXAZEPAM	C				
	RISEDRONIC ACID (RISEDRONATE SODIUM)	C				
	METOPROLOL TARTRATE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Aug-2011	8126415	EXPEDITED (15-DAY)	Y	OT,RI	1000023028	50 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
	LAMICTAL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Aug-2011	8126425	EXPEDITED (15-DAY)	N	HO	1000023030	39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MYELODYSPLASTIC SYNDROME	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DRY MOUTH	OXYCODONE HYDROCHLORIDE	C				
ABDOMINAL PAIN UPPER						
BACK PAIN						
BRUXISM						
CHEST PAIN						
DIZZINESS						
DYSPNOEA						
FATIGUE						
FLATULENCE						
INSOMNIA						
MUSCLE SPASMS						
NIGHT SWEATS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Sep-2011	7987485	EXPEDITED (15-DAY)	Y	CA	1000020997	< 1 DAY	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONGENITAL MUSCULOSKELETAL ANOMALY	LEXAPRO	S	TRANSPLACENTAL	20 MG (20 MG,1 IN 1 D),TRANSPLACENTAL		
Maternal drugs affecting foetus	OXAZEPAM	S	TRANSPLACENTAL	60 MG (60 MG,1 IN 1 D),TRANSPLACENTAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Sep-2011	8082775	EXPEDITED (15-DAY)	N	OT,RI	1000022350	78 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CUTANEOUS LUPUS ERYTHEMATOSUS	LEXAPRO	S	ORAL	10 MG,ORAL		
	LEXAPRO	S	ORAL	15 MG,ORAL		
	LEXAPRO	S	ORAL	10 MG,ORAL		
	LEXAPRO	S	ORAL	5 MG,ORAL		
	EXELON (RIVASTIGMINE) (TRANSDERMAL) (RIVASTIGMINE)	C				
	LEVOTHYROXINE (LEVOTHYROXINE SODIUM) (LEVOTHYROXINE SODIUM)	C				
	NAMENDA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Sep-2011	8135283	EXPEDITED (15-DAY)	Y	HO,OT,RI	1000023186	64 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ASTHENIA	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D),ORAL		
YELLOW SKIN	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D),ORAL		
THROMBOCYTOPENIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Sep-2011	8135408	EXPEDITED (15-DAY)	Y	OT,RI	1000023314		Unknown	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal drugs affecting foetus	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
SMALL FOR DATES BABY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Sep-2011	8122171	EXPEDITED (15-DAY)	N	OT	US-WATSON-2011-13519		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	FIORICET	S	ORAL	UNK		WATSON
TREMOR	PRISTIQ EXTENDED RELEASE	S	UNKNOWN	UNK		
	LEXAPRO	S	UNKNOWN	UNK		
	CYMBALTA	S	UNKNOWN	4 tabs in the morning		
	KLONOPIN	S	UNKNOWN	UNK		
	REGLAN	S	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Sep-2011	8080087	NON-EXPEDITED	N	OT	US-PFIZER INC-2011177274	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIARRHOEA	PRISTIQ EXTENDED RELEASE	S		50 mg, 1x/day	15 DAY	PFIZER
WEIGHT DECREASED	PRISTIQ EXTENDED RELEASE	S				PFIZER
PAIN	PRISTIQ EXTENDED RELEASE	S				PFIZER
FAECES DISCOLOURED	PRISTIQ EXTENDED RELEASE	S				PFIZER
DISTURBANCE IN ATTENTION	PRISTIQ EXTENDED RELEASE	S				PFIZER
CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR	PRISTIQ EXTENDED RELEASE	S				PFIZER
NERVOUSNESS	PRISTIQ EXTENDED RELEASE	S				PFIZER
ASTHENIA	FIORICET	S		UNK		
MICTURITION DISORDER	CYMBALTA	S		4 tablets in the morning		
PERSONALITY CHANGE	CYMBALTA	S				
	CYMBALTA	S				
	LEXAPRO	S		UNK		
	LEXAPRO	S				
	KLONOPIN	C		0.5 mg, as needed		
	ESTRADIOL	C		0.5 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Sep-2011	8126842	EXPEDITED (15-DAY)		OT	PHHY2011BR77449	81 YR	Female	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ULCER	LOSARTAN POTASSIUM	S		50 mg, UNK		NOVARTIS
HAEMORRHAGE	EXELON	S	ORAL	2 mg, UNK		
HAEMATEMESIS	METFORMIN HYDROCHLORIDE	S		500 mg, UNK		
FAECES DISCOLOURED	MEMANTINE HYDROCHLORIDE	S		10 mg, UNK		
DEHYDRATION	LEXAPRO	S		10 mg, UNK		
PRURITUS	LIPIDIL	S		200 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2011	8087096	EXPEDITED (15-DAY)	Y	OT,RI	1000022484	33 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NO ADVERSE EVENT	LEXAPRO	S	ORAL	10 MG (10 M, 1 IN 1 D), ORAL; 10 MG BID (10 MG, 2 IN 1 D), ORAL		
	LORATADINE (LORATADINE) (LORATADINE)	C				
	HYDROCODONE/ ACETAMINOPHEN (HYDROCODONE, ACETAINOPHEN) (HYDROCODONE, ACETAMINOPHEN)	C				
	ZANAFLEX (TIZANIDINE HYDROCHLORIDE) (TIZANIDINE HYDROCHLORIDE)	C				
	MOTRIN	C				
	METHOCARBAMOL (METHOCARBAMOL) (METHACARBAMOL)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2011	8144787	EXPEDITED (15-DAY)	N	OT,RI	1000023211	34 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INFLUENZA	LEXAPRO	S		10 MG (10 MG, 1 IN 1 D)		
ADVERSE EVENT						
AKATHISIA						
ANXIETY						
Balance disorder						
BRAIN INJURY						
BURNING SENSATION						
DEPRESSION						
DEREALISATION						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS						
EMOTIONAL DISORDER						
FEAR						
FEELING ABNORMAL						
FOOD INTOLERANCE						
HALLUCINATION						
HALLUCINATION, VISUAL						
HEADACHE						
HYPERSENSITIVITY						
INFLUENZA LIKE ILLNESS						
INSOMNIA						
MANIA						
MEMORY IMPAIRMENT						
NAUSEA						
NIGHT BLINDNESS						
NIGHTMARE						
PANIC ATTACK						
PARAESTHESIA						
SCREAMING						
SEROTONIN SYNDROME						
TACHYPHRENIA						
TINNITUS						
TREMOR						
UNEVALUABLE EVENT						
VIOLENCE-RELATED SYMPTOM						
VISUAL IMPAIRMENT						
VITAMIN A						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Sep-2011	8151999	EXPEDITED (15-DAY)	Y	OT,RI	1000023637	25 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALCOHOL USE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
LOSS OF CONSCIOUSNESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Sep-2011	8155434	EXPEDITED (15-DAY)	Y	HO	1000023730		Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR	LEXAPRO	S	ORAL	ORAL		
NIGHT SWEATS						
PYREXIA						
RASH						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Sep-2011	8144062	DIRECT	N	OT		40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERTENSION	LEXAPRO	S	ORAL	10mg or 5mg		
ANXIETY						
BLOOD GLUCOSE INCREASED						
DEPRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Sep-2011	6766901	NON-EXPEDITED	Y	OT	US-ASTRAZENECA-2006UW27731	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ERECTILE DYSFUNCTION	SEROQUEL	S	ORAL	25 MG-200 MG, 200 MG 3 PILLS A DAY.		
HAEMOGLOBIN DECREASED	SEROQUEL	S	ORAL	25 MG-200 MG, 200 MG 3 PILLS A DAY.		

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIABETES MELLITUS	SEROQUEL	S	ORAL	25 MG-200 MG, 200 MG 3 PILLS A DAY.		
WEIGHT INCREASED	SEROQUEL	S	ORAL	100 MG-400 MG	774 DAY	
HYPERTRIGLYCERIDAEMIA	SEROQUEL	S	ORAL	100 MG-400 MG	774 DAY	
BLOOD CHOLESTEROL INCREASED	SEROQUEL	S	ORAL	100 MG-400 MG	774 DAY	
LIVER FUNCTION TEST ABNORMAL	LEXAPRO	S	UNKNOWN			
	GEODON	C	ORAL		256 DAY	
	IMIPRAMINE	C	ORAL		4 MTH	
	INVEGA	C			9 MTH	
	ABILIFY	C			32 DAY	
	NEURONTIN	C		300 MG- 1800 MG		
	VITAMIN E	C				
	CLONAZEPAM	C				
	NEXIUM	C				
	TRAZODONE HYDROCHLORIDE	C				
	PAXIL	C		20 MG-40 MG		
	REMERON	C				
	VIAGRA	C				
	NIASPAN	C				
	RANITIDINE	C				
	LIPITOR	C				
	ANDROGEL	C				
	CIPROFLOXACIN	C				
	DIOVAN	C				
	AVANDAMET	C				
	TOPAMAX	C				
	PROTONIX	C	ORAL			
	RISPERDAL	C	ORAL	1 MG - 3 MG		
	KLONOPIN	C		2 MG 1 BID 1 AND 1/2 HS		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Sep-2011	8148323	NON-EXPEDITED	N		US-ASTRAZENECA-2011SE09048		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG SCREEN POSITIVE	SEROQUEL	S	ORAL			ZENECA
	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Sep-2011	8149084	NON-EXPEDITED	N		US-ASTRAZENECA-2011SE35740		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	SEROQUEL	S	ORAL			ZENECA
ANXIETY	LEXAPRO	S	UNKNOWN			
CONDITION AGGRAVATED						
DECREASED APPETITE						
PANIC ATTACK						
PHOBIA						

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Sep-2011	8150101	NON-EXPEDITED	Y		US-ASTRAZENECA-2011SE 12408	25 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SOMNOLENCE	SEROQUEL XR	S	ORAL		1 DAY	ASTRAZENECA
FATIGUE	SEROQUEL XR	S	ORAL		1 DAY	ASTRAZENECA
CONFUSIONAL STATE	SEROQUEL XR	S	ORAL		3 DAY	ASTRAZENECA
DISORIENTATION	SEROQUEL XR	S	ORAL		3 DAY	ASTRAZENECA
	SEROQUEL XR	S	ORAL			ASTRAZENECA
	SEROQUEL XR	S	ORAL			ASTRAZENECA
	LEXAPRO	S	ORAL		1 DAY	
	LEXAPRO	S	ORAL		1 DAY	
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	XANAX	C	ORAL	THREE TABLETS A DAY		
	ADDERALL	C	ORAL	TWO TABLETS A DAY		
	VICODIN HP	C	ORAL	10/660MG AS REQUIRED		
	DEPO-PROVERA	C	INTRAMUSCULAR	ONE IN THREE MONTHS		
	METHADONE HYDROCHLORIDE	C	ORAL			
	MOTRIN	C	ORAL			

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Sep-2011	8150707	NON-EXPEDITED	N		US-ASTRAZENECA-2010SE57629	79 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VISION BLURRED	SEROQUEL	S	ORAL			ZENECA
DYSURIA	TOVIAZ	S	ORAL		5 DAY	
CONSTIPATION	XANAX	S	UNKNOWN			
DRY MOUTH	ZOCOR	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	FISH OIL	S	UNKNOWN			
	ACETYLSALICYLIC ACID	S	UNKNOWN			
	VITAMIN D	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Sep-2011	8150825	NON-EXPEDITED	N	OT	US-ASTRAZENECA-2011SE41665	62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	SEROQUEL	S	ORAL			ZENECA
	SEROQUEL	S	ORAL			ZENECA
	ATIVAN	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Sep-2011	8150967	NON-EXPEDITED	N	OT	US-ASTRAZENECA-2011SE06856		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	SEROQUEL	S	ORAL			ZENECA
SWELLING FACE	MIRALAX	S	ORAL			
OEDEMA PERIPHERAL	LEXAPRO	S	ORAL			
	TOPAMAX	S	ORAL			
	NEURONTIN	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Sep-2011	8151387	NON-EXPEDITED		HO	US-ASTRAZENECA-2010SE59766	48 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	SEROQUEL XR	S	ORAL		31 DAY	
FATIGUE	LEXAPRO	S	UNKNOWN			
	XANAX	S	UNKNOWN			
	LISINOPRIL	C	ORAL			
	CYMBALTA	C	ORAL			
	OXYCODONE HYDROCHLORIDE	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Sep-2011	8151740	NON-EXPEDITED	N		US-ASTRAZENECA-2010SE38417	77 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	SEROQUEL	S	ORAL			ZENECA
ANXIETY	DOXEPIN	C				
	VITAMIN B12	C				
	COLACE	C				
	SIMETHICONE	C				
	LAMICTAL	C				
	RISPERDAL	C				
	GEMFIBROZIL	C				
	ACIPHEX	C				
	LEXAPRO	S	ORAL		4 DAY	
	LEXAPRO	S	ORAL			
	ATIVAN	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Sep-2011	8157992	DIRECT	Y	HO,DS,CA		< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CRANIOSYNOSTOSIS	LEXAPRO	S	ORAL	10MG 1 PO DAILY		FOREST
BICUSPID AORTIC VALVE						
DILATATION VENTRICULAR						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Sep-2011	8084511	EXPEDITED (15-DAY)	Y	DE,HO	1000022513	70 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PULMONARY HYPERTENSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	SIMVASTATIN (SIMVASTATIN) (TABLETS) (SIMVASTATIN)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Sep-2011	8170165	EXPEDITED (15-DAY)	N	HO	1000024018	90 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GASTROINTESTINAL HAEMORRHAGE	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL; 10 MG (10 MG, 1 IN 1 D), ORAL		
DIVERTICULITIS	PROSCAR	C				
FATIGUE	FERROUS SULFATE	C				
POOR QUALITY SLEEP	NEXIUM	C				
HAEMOGLOBIN DECREASED	STOOL SOFTENER (DOCUSATE SODIUM)	C				
	CENTRUM SILVER MULTIVITAMIN	C				
	LISINOPRIL	C				
	SIMVASTATIN	C				
	NORVASC	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Sep-2011	8171488	EXPEDITED (15-DAY)	Y	OT,RI	1000023962		Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
LISTLESS	MIRTAZAPINE	C				
DEPENDENT PERSONALITY DISORDER						
DEPRESSED MOOD						
HYPERVENTILATION						
PANIC ATTACK						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Sep-2011	8158152	NON-EXPEDITED			US-PFIZER INC-2011224017	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	PENICILLIN G BENZATHINE/ PENICILLIN G PROCAINE	S		UNK		UNKNOWN
	Dilantin	S		UNK		PFIZER
	IBUPROFEN	S		UNK		PFIZER
	LIDOCAINE HCL	S		UNK		PFIZER
	BACLOFEN	S		UNK		
	ACETYLSALICYLIC ACID	S		UNK		
	LEXAPRO	S		UNK		
	TORADOL	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Sep-2011	8162343	EXPEDITED (15-DAY)	N	OT	GXBR2011US04775	90 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TRANSIENT ISCHAEMIC ATTACK	LORATADINE	S	ORAL	10 mg, QD		NOVARTIS
VITREOUS FLOATERS	LEXAPRO	S		5 mg, UNK		
ARTHRITIS	LEXAPRO	S		10 mg, UNK		
INTERVERTEBRAL DISC COMPRESSION						
INTERVERTEBRAL DISC DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Sep-2011	8170974	DIRECT	Y	HO,DS,CA		< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PREMATURE CLOSURE OF CRANIAL SUTURES	LEXAPRO	S	ORAL	LEXAPRO 10MG 1 PO DAILY 2004 OR 5 - 2009		
BICUSPID AORTIC VALVE						
LEFT VENTRICULAR HYPERTROPHY						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Sep-2011	8748963	DIRECT	N	DE,OT		35 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal drugs affecting foetus	LEXAPRO	S				
SUDDEN INFANT DEATH SYNDROME	LAMICTAL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Oct-2011	8182639	EXPEDITED (15-DAY)	Y	OT,RI	1000024244	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FUNGAL INFECTION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
DRUG INTERACTION	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL ; 10 MG (10 MG,1 IN 1 D),ORAL		
DEPRESSION	FLUCONAZOLE	S	ORAL	DAILY (1 IN 1 D),ORAL		
FATIGUE	DEPLIN (CALCIUM LEVOMEFOLATE) (CALCIUM LEVOMEFOLATE)	C				
MANIA						
PALPITATIONS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Oct-2011	8184283	EXPEDITED (15-DAY)	Y	HO	1000024341	74 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CIRCULATORY COLLAPSE	LEXAPRO	S		10 MG (1 TIME)		
ELECTROCARDIOGRAM QT PROLONGED	ATENOLOL (ATENOLOL)	S	ORAL	50 MG (1 TIME),ORAL		
FALL	ASPIRIN	S		150 MG (1 TIME)		
CONTUSION	ATORVASTATIN CALCIUM	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Oct-2011	6994733	EXPEDITED (15-DAY)	Y	DE	1000005980	7 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
IMPULSIVE BEHAVIOUR	SYMBYAX	S		3MG/25MG (1 IN 1 D),		
ABNORMAL BEHAVIOUR	VYVANSE	S	ORAL	30 MG (30 MG, 1 IN 1 D), ORAL; 50 MG (50 MG, 1 IN 1 D), ORAL		
AGGRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Oct-2011	7596043	EXPEDITED (15-DAY)	Y	OT,RI	1000016080		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LEXAPRO	S	ORAL	ORAL		
SEROTONIN SYNDROME	ZOLOFT	S				
JOINT LOCK	WELLBUTRIN	S				
FEELING ABNORMAL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Oct-2011	8160545	EXPEDITED (15-DAY)	Y		US-PURDUE-USA-2010-0048602	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ENERGY INCREASED	OXYCONTIN	S		80 mg, q8h		PURDUE
INADEQUATE ANALGESIA	LEXAPRO	S	ORAL	10 mg, UNK	11 DAY	
ANXIETY	ZOLOFT	S	ORAL	100 mg, UNK	38 DAY	
PRODUCT FORMULATION ISSUE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Oct-2011	8186287	EXPEDITED (15-DAY)	N	CA	1000024402	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC MURMUR	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
ATRIAL SEPTAL DEFECT						
Maternal drugs affecting foetus						
PATENT DUCTUS ARTERIOSUS						
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Oct-2011	8175876	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-16114514	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION	GLUCOPHAGE	S			4 YR	BRISTOL MYERS SQUIBB
BLOOD GLUCOSE INCREASED	LEXAPRO	S				
FALL	WELLBUTRIN	C				
MUSCULOSKELETAL CHEST PAIN	XANAX	C				
ABDOMINAL PAIN UPPER	FENTANYL PATCH	C		started 5yrs ago		
NAUSEA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2011	8194913	EXPEDITED (15-DAY)	Y	OT,RI	1000024459		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NEPHROLITHIASIS	LEXAPRO	S		20 MG (20 MG, 1 IN 1 D)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	7701166	NON-EXPEDITED	N	OT	1000014928	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SYNCOPE	LEXAPRO	S	ORAL	SEE IMAGE		
BLOOD THYROID STIMULATING HORMONE DECREASED	LEXAPRO	S	ORAL	SEE IMAGE		
	NEXIUM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	7701205	NON-EXPEDITED	Y	DE	1000014986	19 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ACCIDENTAL OVERDOSE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
MANIA	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL; 15 MG (15 MG, 1 IN 1 D),ORAL		
	XANAX	S	ORAL	0.5 MG TID PRN, ORAL		
	VICODIN	S	ORAL	ORAL		
	ALCOHOL	S	ORAL	ORAL		
	SEROQUEL XR	S	ORAL	100 MG (100 MG, 1 IN 1 D), ORAL		
	TRAZODONE HYDROCHLORIDE	C				
	ULTRAM	C				
	IMITREX	C				
	SKELAXIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225598	NON-EXPEDITED	Y	RI	1000018065	40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL		
DRUG INEFFECTIVE	WELLBUTRIN	S				
BIPOLAR DISORDER	TRAZODONE (TRAZODONE) (TABLETS) (TRAZODONE)	C				
CRYING	TOPAMAX (TOPIRAMATE) (TOPIRAMATE)	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225618	NON-EXPEDITED	N	OT,RI	1000018159	31 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
DEPRESSION	ALPRAZOLAM (ALPRAZOLAM) (1 MILLIGRAM, TABLETS) (ALPRAZOLAM)	C				
MOOD SWINGS	TRAMADOL (TRAMADOL) (50 MILLIGRAM, TABLETS) (TRAMADOL)	C				
CRYING						
PARANOIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225622	NON-EXPEDITED	Y	OT,RI	1000018260	25 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
STOMATITIS	XANAX	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225647	NON-EXPEDITED	Y	OT,RI	1000018377	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NEPHROLITHIASIS	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL ; 20 MG (20 MG,1 IN 1 D),ORAL		
MYALGIA	LEXAPRO	S	ORAL	40 MG (40 MG,1 IN 1 D),ORAL ; 20 MG (20 MG,1 IN 1 D),ORAL ; 30 MG, (30 MG,1 IN 1 D),ORAL		
HYPERSOMNIA	LIPITOR	S				
OVERDOSE	NADOLOL (NADOLOL) (NADOLOL)	C				
	DEXEDRINE (DEXAMFETAMINE SULFATE) (DEXAMFETAMINE SULFATE)	C				
	ADDERALL (AMPHETAMINE, DEXTROAMPHETAMINE) (AMPHETAMINE, DEXTROAMPHETAMINE)	C				
	PRAVASTATIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225668	NON-EXPEDITED	Y	OT,RI	1000018695	11 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL ; 15 MG (15 MG,1 IN 1 D),ORAL		
SUICIDAL IDEATION	ABILIFY (ARIPIPRAZOLE) (5 MILLIGRAM, TABLETS) (ARIPIPRAZOLE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225669	NON-EXPEDITED	N	OT,RI	1000018998	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	(1 IN 1 D),ORAL		
DEPRESSION	VITAMIN B-12 (CYANOCOBALAMIN) (CYANOCOBALAMIN)	C				
	VICODIN (HYDROCODONE) (HYDROCODONE)	C				
	LISINOPRIL	C				
	SIMVASTATIN	C				
	OMEPRAZOLE	C				
	NIFEDIPINE	C				
	CARVEDILOL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225678	NON-EXPEDITED	Y	HO	1000019254	44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	LEXAPRO	S	ORAL	ORAL ; ORAL		
SUICIDE ATTEMPT	LUNESTA	S	ORAL	2 MG (2 MG,1 IN 1 D),ORAL ; ORAL		
	AMBIEN CR	S	ORAL	12.5 MG (12.5 MG,1 IN 1 D),ORAL ; ORAL		
	XANAX	S	ORAL	ORAL ; ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225707	NON-EXPEDITED	N	HO	1000019281	16 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
INTENTIONAL OVERDOSE	OXYCONTIN	S	ORAL	ORAL		
	UNSPECIFIED INGREDIENT	S	ORAL	ORAL		
	UNSPECIFIED INGREDIENT	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225711	NON-EXPEDITED	N	OT,RI	1000019386	28 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225715	NON-EXPEDITED	N	HO,OT	1000019477	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225763	NON-EXPEDITED	N	OT	1000015749	53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRY MOUTH	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL 5 MG (5 MG, 1 IN 1 D), ORAL 2.5 (2.5 MG, EVERY OTHER DAY), ORAL		
FEELING ABNORMAL	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
THIRST	KEPPRA	S				
PAIN	SYNTHROID	C				
WEIGHT INCREASED	BABY ASPIRIN	C				
CRYING						
PRODUCTIVE COUGH						
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225768	NON-EXPEDITED	Y	DE	1000015826	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL		
	KLONOPIN (CLONAZEPAM) (0.5 MILLIGRAM, TABLETS) (CLONAZEPAM)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225780	NON-EXPEDITED	N	OT	1000015921		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	LEXAPRO	S				
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225830	NON-EXPEDITED	N	OT	1000015938	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL 10 MG (10 MG, 1 IN 1 D), ORAL		
SUICIDAL IDEATION	BACLOFEN	C				
DIZZINESS	ASPIRIN	C				
FATIGUE						
MANIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225873	NON-EXPEDITED	Y	OT	1000016212		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	LEXAPRO	S				
	ZOLOFT	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8225879	NON-EXPEDITED	Y	OT	1000016476	35 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PARKINSONISM	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226014	NON-EXPEDITED	N	OT	1000016592	17 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSTONIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	TRAZODONE (TRAZODONE) (TABLETS) (TRAZODONE)	C				
	GEODON (ZIPRASIDONE) (ZIPRASIDONE)	C				
	PROPRANOLOL	C				
	FOCALIN XR (DEXMETHYLPHENIDATE HYDROCHLORIDE) (DEXMETHYLPHENIDATE HYDROCHLORIDE)	C				
	TOPAMAX (TOPIRAMATE) (TOPIRAMATE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226022	NON-EXPEDITED	N	HO	1000016758	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CHEST PAIN	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
TREMOR	AZOR (AMLODIPINE, OLMESARTAN) (AMLODIPINE, OLMESARTAN)	C				
HYPERHIDROSIS	XYZAL (LEVOCETIRIZINE DIHYDROCHLORIDE) (LEVOCETIRIZINE DIHYDROCHLORIDE)	C				
PARAESTHESIA	PRILOSEC (OMEPRAZOLE) (OMEPRAZOLE)	C				
ELECTROCARDIOGRAM CHANGE						
NAUSEA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226048	NON-EXPEDITED	Y	OT	1000016800		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226073	NON-EXPEDITED	Y	OT	1000016801		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226088	NON-EXPEDITED	Y	OT	1000016802		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226108	NON-EXPEDITED	N	DE	1000022739	44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	LEXAPRO	S		10 MG (10 MG, 1 IN 1 D)		
AGITATION						
ANXIETY						
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226110	NON-EXPEDITED	Y	OT,RI	1000017219	43 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	30 MG (30 MG, 1 IN 1 D), ORAL		
DRUG INEFFECTIVE	ZOLOFT	S	ORAL	ORAL		
OVERDOSE	CYMBALTA	S	ORAL	60 MG (60 MG, 1 IN 1 D), ORAL		
FATIGUE	WELLBUTRIN	S	ORAL	ORAL		
SOMNOLENCE	METHADONE (METHADONE) (METHADONE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226131	NON-EXPEDITED	N	HO	1000017235	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANIC ATTACK	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
SUPRAVENTRICULAR TACHYCARDIA	METOPROLOL (METOPROLOL) (TABLETS) (METOPROLOL)	C				
BLOOD PRESSURE DECREASED	LEVOTHYROXINE SODIUM	C				
SUICIDAL IDEATION	OMEPRAZOLE	C				
AGITATION	XANAX (ALPRAZOLAM) (0.25 MILLIGRAM, TABLETS) (ALPRAZOLAM)	C				
TREMOR	DECADRON (DEXAMETHASONE) (TABLETS) (DEXAMETHASONE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226132	NON-EXPEDITED	N	OT,RI	1000013431	18 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
SOMNOLENCE	BIRTH CONTROL (NOS) (CONTRACEPTIVES NOS) (CONTRACEPTATIVES NOS)	C				
GLYCOSYLATED HAEMOGLOBIN DECREASED						
GLYCOSYLATED HAEMOGLOBIN INCREASED						
HYPOMANIA						
IRRITABILITY						
TYPE 2 DIABETES MELLITUS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226197	NON-EXPEDITED	Y	OT,RI	1000019506	38 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226199	NON-EXPEDITED	Y	HO	1000014465	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPONATRAEMIA	LEXAPRO	S	ORAL	10 MG(10 MG, 1 IN 1 D), ORAL		
	LISINOPRIL	C				
	ATENOLOL	C				
	SIMVASTATIN	C				
	XANAX	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226202	NON-EXPEDITED	Y	OT,RI	1000017296		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR TACHYCARDIA	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226215	NON-EXPEDITED	Y	OT,RI	1000021173	9 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGGRESSION	LEXAPRO	S				
INCORRECT ROUTE OF DRUG ADMINISTRATION	NASONEX	S		NASAL		
	ASMANEX	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226217	NON-EXPEDITED	N	OT,RI	1000021426		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S				
SUICIDE ATTEMPT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226225	NON-EXPEDITED	Y	OT,RI	1000021607		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
APLASTIC ANAEMIA	LEXAPRO	S		10 MG		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226226	NON-EXPEDITED	Y	HO	1000017394	31 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABORTION MISSED	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
MATERNAL EXPOSURE DURING PREGNANCY	PRENATAL VITAMINS WITH DHA (PRENATAL VITAMINS WITH DHA) (PRENATAL VITAMINS WITH DHA)	C				
URINARY TRACT INFECTION	RETIN A GEL 0.1% (TRETINOIN) (TRETINOIN)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226229	NON-EXPEDITED	N	OT,RI	1000021610	25 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226243	NON-EXPEDITED	N	OT	1000019507	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ANXIETY						
NIGHT SWEATS						
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226244	NON-EXPEDITED	Y	HO	1000022068		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOMANIA	LEXAPRO	S				
	ZOLOFT	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226245	NON-EXPEDITED	Y	HO	1000017468	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPONATRAEMIA	LEXAPRO	S				
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226247	NON-EXPEDITED	Y	OT	1000022296		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226252	NON-EXPEDITED	N	HO	1000019547	53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABDOMINAL PAIN UPPER	LEXAPRO	S	ORAL	20 MG (20 MG), ORAL		
DISTURBANCE IN ATTENTION						
FEELING ABNORMAL						

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226256	NON-EXPEDITED	N	OT,RI	1000022437	75 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
AMNESIA	LEXAPRO	S	ORAL	15 MG (15 MG, 1 IN 1 D), ORAL, 10 MG (10 MG, 1 IN 1 D), ORAL		
INSOMNIA	DIOVAN	C				
MENTAL IMPAIRMENT	METFORMIN HYDROCHLORIDE	C				
AGGRESSION	SIMVASTATIN	C				
HEADACHE	CILOSTAZOL (CILOSTAZOL) (CILOSTAZOL)	C				
FOOD CRAVING	HYDROCODONE (HYDROCODONE) (HYDROCODONE)	C				
	LOSARTAN HYDROCHLOROTHIAZIDE (LOSARTAN, HYDROCHLOROTHIAZIDE) (LOSARTAN, HYDROCHLOROTHIAZIDE)	C				
	METOPROLOL SUCCINATE	C				
	LEVOTHYROXINE (LEVOTHYROXINE SODIUM) (LEVOTHYROXINE SODIUM)	C				
	PRILOSEC (OMEPRAZOLE) (OMEPRAZOLE)	C				
	ALKA SELTZER (SODIUM BICARBONATE, CITRIC ACID, ASPIRIN) (SODIUM BICARBONATE, CITRIC ACID, ASPIRIN)	C				

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226261	NON-EXPEDITED	Y	OT,RI	1000019668	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ELECTROCARDIOGRAM QT PROLONGED	LEXAPRO	S	ORAL	ORAL		
	VIBATIV	S	INTRAVENOUS	10 MG/KG TOTAL DAILY DOSE, INTRAVENOUS (NOT OTHERWISE SPECIFIED)		
	TRAZODONE HYDROCHLORIDE	S	ORAL	ORAL		
	REGLAN	C				
	WARFARIN SODIUM	C				
	NOVOLIN R	C				
	HYDROMORPHONE HYDROCHLORIDE	C				
	METOPROLOL TARTRATE	C				
	LISINOPRIL	C				
	SITAGLIPTIN	C				
	IMDUR	C				
	LASIX	C				
	CILOSTAZOL	C				
	VITAMIN D (COLECALCIFEROL)	C				
	CALCIUM CITRATE	C				
	OMEPRAZOLE	C				
	ZOLPIDERM	C				
	LIPITOR	C				
	FENTANYL	C				
	LANTUS	C				
	OXYCODONE HYDROCHLORIDE	C				

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226263	NON-EXPEDITED	N	OT,RI	1000022542	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
	HALDOL (HALOPERIDOL) (HALOPERIDOL)	C				
	NEXIUM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226266	NON-EXPEDITED	N	LT	1000020040		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	ORAL		
DRUG INEFFECTIVE	ABILIFY	S	ORAL	ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226267	NON-EXPEDITED	N	OT,RI	1000017752	75 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERTENSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	SYNTHROID (LEVOTHYROXINE SODIUM) (50 MICROGRAM, TABLETS) (LEVOTHYROXINE SODIUM)	C				
	ALENDRONATE (ALENDRONATE SODIUM) (ALENDRONATE SODIUM)	C				
	AMBIEN (ZOLPIDEM TARTRATE) (5 MILLIGRAM, TABLETS) (ZOLPIDEM TARTRATE)	C				
	SIMVASTATIN (SIMVASTATIN) (20 MILLIGRAM, TABLETS) (SIMVASTATIN)	C				
	CENTRUM VITAMINS (CENTRUM VITAMINS) (CENTRUM VITAMINS)	C				
	CALCIUM (CALCIUM) (CALCIUM)	C				
	VITAMIN D (VITAMIN D) (VITAMIN D)	C				
	VIACTIV (CALCIUM) (CALCIUM)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226271	NON-EXPEDITED	N	OT,RI	1000020557		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	LEXAPRO	S		ORAL		
INTENTIONAL OVERDOSE	UNSPECIFIED INGREDIENT	S				
OVERDOSE						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226272	NON-EXPEDITED	Y	HO	1000022690		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANCREATITIS	LEXAPRO	S				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226273	NON-EXPEDITED	Y	OT	1000017836	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	LEXAPRO	S	ORAL	ORAL		
	NEURONTIN	S	ORAL	ORAL		
	OXYCONTIN (OXYCODONE HYDROCHLORIDE) (OXYCODONE HYDROCHLORIDE)	C				
	MORPHINE SULFATE	C				
	DIAZEPAM	C				
	VICODIN ER (HYDROCODONE, ACETAMINOPHEN) (HYDROCODONE, ACETAMINOPHEN)	C				
	SOMA (CARISOPRODOL) (CARISOPRODOL)	C				
	PARAFON FORTE (CHLORZOXAZONE) (CHLORZOXAZONE)	C				
	ZANAFLEX (TIZANIDINE HYDROCHLORIDE) (TIZANIDINE HYDROCHLORIDE)	C				
	KLONOPIN	C				
	ATIVAN	C				
	PHENERGAN (PROMETHAZINE) (PROMETHAZINE)	C				
	RELAFEN (NABUMETONE) (NABUMETONE)	C				
	LIDODERM (LIDOCAINE) (POULTICE OR PATCH) (LIDOCAINE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226301	NON-EXPEDITED	N	OT	1000020784	67 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S		10 MG (10 MG, 1 IN 1 D), ORAL; 10 MG EVERY OTHER DAY (10 MG, 1 IN 2 D), ORAL		
FEELING JITTERY	SEROQUEL	C				
ANXIETY	XANAX	C				
	SYNTHROID	C				
	COREG	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226302	NON-EXPEDITED	Y	OT,RI	1000018027		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S				
DEPRESSION	INVEGA	S	ORAL	ORAL		
SOMNOLENCE						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226314	NON-EXPEDITED	Y	HO	1000020983		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPONATRAEMIA	LEXAPRO	S				
ASTHENIA						
CONFUSIONAL STATE						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8226330	NON-EXPEDITED	Y	HO	1000020984	80 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPONATRAEMIA	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ASTHENIA	CLONAZEPAM	C				
FATIGUE	VYTORIN	C				
	ASPIRIN	C				
	CARBAMAZEPINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8228485	NON-EXPEDITED	N	OT,RI	1000017454	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT DECREASED	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
INSOMNIA	AMBIEN	C				
NERVOUSNESS	GLYBURIDE	C				
DISTURBANCE IN ATTENTION	VYTORIN (INEGY) (INEGY)	C				
HEADACHE	CALCIUM (CALCIUM) (CALCIUM)	C				
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8228577	NON-EXPEDITED	N	OT,RI	1000021106	47 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INTENTIONAL OVERDOSE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL, 250 MG, ORAL		
DIZZINESS						
SUICIDE ATTEMPT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8236433	NON-EXPEDITED	Y	OT,RI	10000015444	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANGIOEDEMA	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D),ORAL		
URTICARIA	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D),ORAL		
	VESICARE	C				
	SIMVASTATIN	C				
	COUMADIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2011	8239074	NON-EXPEDITED	Y	HO	10000820982		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPONATRAEMIA	LEXAPRO	S				
ASTHENIA						
CONFUSIONAL STATE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Oct-2011	8183271	DIRECT	N	DE		39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	LEXAPRO	S				
Asphyxia						
Completed suicide						
Feeling abnormal						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Oct-2011	8174969	EXPEDITED (15-DAY)	Y	OT,RI	1000024082	41 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	LEXAPRO	S	ORAL	SEE IMAGE		
VOMITING	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D),ORAL		
DIZZINESS	ALPRAZOLAM	C				
AGITATION						
DECREASED APPETITE						
FATIGUE						
HEADACHE						
HYPERHIDROSIS						
PALPITATIONS						
PARAESTHESIA						
SINUSITIS						
SUICIDAL IDEATION						
TINNITUS						
WEIGHT DECREASED						
WITHDRAWAL SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Oct-2011	8185810	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2011248798	53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	CHANTIX	S	ORAL	0.5 mg, daily		PFIZER
ALCOHOL INTERACTION	CHANTIX	S	ORAL	1 mg, 2x/day		PFIZER
	LEXAPRO	S	ORAL	10 mg, daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Oct-2011	8202173	EXPEDITED (15-DAY)	Y	OT,RI	1000024535		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OESOPHAGEAL ACHALASIA	LEXAPRO	S		10 MG (10 MG)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Oct-2011	8170912	EXPEDITED (15-DAY)	Y	CA	1000024030	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BICUSPID AORTIC VALVE	LEXAPRO	S	TRANSPLACENTAL	(10 MG),TRANSPLACENTAL		
AORTIC VALVE DISEASE	PRENATAL VITAMINS (PRENATAL VITAMINS) (PRENATAL VITAMINS)	C				
APHASIA						
CRANIOSYNOSTOSIS						
Maternal drugs affecting foetus						
MENTAL RETARDATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Oct-2011	8189740	EXPEDITED (15-DAY)	Y	HO	AU-PFIZER INC-2011245315		Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEPATITIS	PRISTIQ EXTENDED RELEASE	S				PFIZER
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Oct-2011	8189948	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2011245079		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BIPOLAR DISORDER	ZOLOFT	S		UNK		PFIZER
PAIN	LEXAPRO	S		UNK		
	OXYCONTIN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Oct-2011	8195052	DIRECT	N	OT,RI		55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SKIN ODOUR ABNORMAL	CYMBALTA	S		1 PILL @ BEDTIME 1 - 1 1/2 YRS	12 MTH	
WEIGHT INCREASED	LEXAPRO	S		1 PILL @ BEDTIME	3 MTH	
ABASIA						
HYPERHIDROSIS						
VEIN DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Oct-2011	8187875	EXPEDITED (15-DAY)	Y	DE,HO	IE-ASTRAZENECA-2011SE 61980	76 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ACUTE HEPATIC FAILURE	SEROQUEL	S	ORAL			
HEPATITIS	NEXIUM	S	ORAL			
	RIFADIN	S	ORAL		5 DAY	
	FUCIDIN	S	UNKNOWN			
	LEXAPRO	S	ORAL			
	AUGMENTIN	S	UNKNOWN	875/125 MG		
	METRONIDAZOLE	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Oct-2011	8194074	NON-EXPEDITED	Y		US-PFIZER INC-2011252344		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD CHOLESTEROL INCREASED	LIPITOR	S	ORAL	10 mg, 1x/day		PFIZER
	LEXAPRO	S	ORAL	10 mg, 1x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Oct-2011	8194817	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20111008995		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD TRIGLYCERIDES INCREASED	CONCERTA	S	UNKNOWN			
	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Oct-2011	8216894	EXPEDITED (15-DAY)	N	CA	1000024784	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TALIPES	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Oct-2011	8163288	EXPEDITED (15-DAY)	Y	OT	US-SANOFI-AVENTIS-2011SA063852	82 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR TACHYCARDIA	MULTAQ	S	ORAL			
ELECTROCARDIOGRAM QT PROLONGED	LEXAPRO	S	UNKNOWN			
BUNDLE BRANCH BLOCK LEFT	ASPIRIN	C				
	XANAX	C				
	ACIPHEX	C				
	DABIGATRAN ETEXILATE	C				
	METOPROLOL TARTRATE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Oct-2011	8199520	DIRECT	N	OT		50 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	LEXAPRO	S	ORAL	10mg		
VERTIGO						
VISUAL IMPAIRMENT						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Oct-2011	8201174	EXPEDITED (15-DAY)	N	OT	BR-PFIZER INC-2011251253	42 YR	Female	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LYRICA	S	ORAL	75 mg, 1 capsule daily	7 DAY	PFIZER
	LYRICA	S	ORAL	150mg (two capsules of 75mg), daily		PFIZER
	ALPRAZOLAM	S		UNK		PFIZER
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Oct-2011	6549166	EXPEDITED (15-DAY)	N	OT,RI	S08-USA-00249-01	24 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRODUCT QUALITY ISSUE	LEXAPRO	S	ORAL	20 MG (10 MG, 2 IN 1 D), ORAL		
SUICIDE ATTEMPT	SERTRALINE HYDROCHLORIDE	S				
AGGRESSION	HYPERICUM	S		900 MG (900 MG, 1 IN 1 D)		
AGITATION						
AKATHISIA						
ANXIETY						
DEPRESSION						
DISCOMFORT						
EJACULATION FAILURE						
FEELING ABNORMAL						
FEELING OF DESPAIR						
IMPULSIVE BEHAVIOUR						
IRRITABILITY						
MANIA						
NERVOUSNESS						
PALPITATIONS						
PARANOIA						
PERSONALITY CHANGE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Oct-2011	8228618	EXPEDITED (15-DAY)	N	CA	1000024864	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FALLOT'S TETRALOGY	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus						
PATENT DUCTUS ARTERIOSUS						
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Oct-2011	8228703	EXPEDITED (15-DAY)	Y	DE,HO	1000024878	76 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BACTERIAL INFECTION	LEXAPRO	S	ORAL	(15 MG),ORAL		
HEPATITIS	NEXIUM	S		(40 MG)		
ACUTE HEPATIC FAILURE	SEROQUEL	S		(25 MG)		
CONFUSIONAL STATE	AUGMENTIN	S	ORAL	ORAL		
AGITATION	METRONIDAZOLE	S	ORAL	400 MG,ORAL		
DEHYDRATION	FUSIDIC ACID	S	ORAL	500 MG (250 MG, 2 IN 1 D),ORAL		
ESCHERICHIA INFECTION	RIFADIN	S	ORAL	600 MG (300 MG, 2 IN 1 D),ORAL		
CARDIAC FAILURE						
SKIN ULCER						
STAPHYLOCOCCAL INFECTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Oct-2011	8232509	EXPEDITED (15-DAY)	N	HO	1000024810	37 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
IMPAIRED DRIVING ABILITY	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
ENCEPHALOPATHY	IRON (IRON) (IRON)	C				
DRUG SCREEN FALSE POSITIVE	CLONAZEPAM	C				
OFF LABEL USE	ARMOUR THYROID (THYROID) (THYROID)	C				
DYSARTHRIA						
MENTAL STATUS CHANGES						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Oct-2011	8233317	EXPEDITED (15-DAY)	Y	OT,RI	1000024976	20 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING ABNORMAL	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DEPRESSION	ZYPREXA	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
GRAND MAL CONVULSION	FLUNITRAZEPAM	S	ORAL	2 MG (2 MG, 1 IN 1 D), ORAL; 5 MG (5 MG, 1 IN 1 D), ORAL		
CONFUSIONAL STATE	BROTIZOLAM	S	ORAL	0.25 MG (0.25 MG, 1 IN 1 D), ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Nov-2011	8236845	NON-EXPEDITED	N	OT	DSA_44544_2010	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	ATIVAN	S		NOT THE PRESCRIBED AMOUNT		
	NEURONTIN	S		DF		
	OXYCONTIN	S		DF		
	MORPHINE SULFATE	S		DF		
	DIAZEPAM	S		DF		
	VICODIN	S		DF		
	SOMA	S		DF		
	PARAFON FORTE	S		DF		
	ZANAFLEX	S		DF		
	KLONOPIN	S		DF		
	PHENERGAN	S		DF		
	LEXAPRO	S		DF		
	RELAFEN	S		DF		
	LIDODERM	S		DF		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Nov-2011	8200237	EXPEDITED (15-DAY)	Y	LT	1000024644	< 1 DAY	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FOETAL EXPOSURE DURING PREGNANCY	LEXAPRO	S	TRANSPLACENTAL	20 MG (20 MG, 1 IN 1 D),TRANSPLACENTAL		
NEONATAL RESPIRATORY DEPRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Nov-2011	8200639	EXPEDITED (15-DAY)	Y	HO	1000024702		Unknown	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VICTIM OF SEXUAL ABUSE	LEXAPRO	S	ORAL	ORAL		
INJURY						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Nov-2011	8190093	EXPEDITED (15-DAY)	Y	OT,RI	1000024312	71 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NO ADVERSE EVENT	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	ZYPREXA	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	TRAZODONE HYDROCHLORIDE	S		300 MG (300 MG, 1 IN 1 D);		
	PRISTIQ EXTENDED RELEASE	S	ORAL	(50 MG, EVERY OTHER DYA), ORAL		
	BENICAR	C				
	CYMBALTA	C				
	LEVOTHROID	C				
	OMEGA 3 FATTY ACIDS	C				
	ATIVAN	C				
	SPECTRAVITE (MULTIVITAMINS)	C				
	VIATMIN D3 (COLECALCIFEROL)	C				
	DEPLIN (CALCIUM LEVOMEFOLATE)	C				
	TOPROL XL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Nov-2011	8202779	EXPEDITED (15-DAY)	Y	OT	AU-ABBOTT-11P-008-0866676-00	49 YR	Male	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	VALPROIC ACID	S				
PANIC ATTACK	LEXAPRO	S				
	CAFFEINE CITRATE	S	ORAL			
	EFFEXOR XR	S				
	HYPERICUM PERFORATUM	S				
	LITHIUM	S				
	ABILIFY	S				
	ALVESCO	S				
	PANTOPRAZOLE	C				
	GLUCOSAMINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Nov-2011	8239347	EXPEDITED (15-DAY)	N	CA	1000025091		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINA BIFIDA OCCULTA	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
FOETAL EXPOSURE DURING PREGNANCY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Nov-2011	8240861	EXPEDITED (15-DAY)	Y	OT,RI	1000025118	24 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
LOSS OF CONSCIOUSNESS	AMOXAPINE	C				
	MEILAX (ETHYL LOFLAZEPATE)	C				
	DOGMATYL (SULPIRIDE)	C				
	AMOBAN (ZOPICLONE)	C				
	GASTER (OMEPRAZOLE)	C				
	METLIGINE (MIDODRINE HYDROCHLORIDE)	C				
	INDERAL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Nov-2011	8242675	DIRECT	N	HO,OT,RI			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PYREXIA	LEXAPRO	S		10MG 1X PER DAY		
BLOOD CHOLESTEROL INCREASED						
DYSGEUSIA						
HYPERTENSION						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Nov-2011	8245906	DIRECT	N	OT,RI		29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	LEXAPRO	S	ORAL	20MG 1XD ORAL		
ABNORMAL BEHAVIOUR						
AGGRESSION						
DRUG INEFFECTIVE						
MOOD SWINGS						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Nov-2011	8246219	EXPEDITED (15-DAY)	Y	OT	USA/USA/11/0021819		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	AUGMENTIN	S	ORAL	875 MG, 2 IN 1 D, ORAL		
DEPRESSION	ABILIFY	S				
	TOPAMAX	S				
	LEXAPRO	S				
	SEROQUEL	S				
	VIMPAT	C				
	METFORMIN HYDROCHLORIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Nov-2011	8239736	NON-EXPEDITED	N		US-ASTRAZENECA-2011SE 51937	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALOPECIA	LISINOPRIL	S	ORAL			ZENECA
DRUG INTERACTION	TOPROL XL	S	ORAL			
	LEXAPRO	S	ORAL			
	SIMVASTATIN	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Nov-2011	7962169	EXPEDITED (15-DAY)	N	OT,RI	1000020555	29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GASTRIC DILATATION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
HAEMORRHOIDS	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
COLITIS ULCERATIVE						
OFF LABEL USE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Nov-2011	8254323	EXPEDITED (15-DAY)	Y	OT,RI	1000025141	82 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR TACHYCARDIA	LEXAPRO	S		(20 DOSAGE FORMS)		
ELECTROCARDIOGRAM QT PROLONGED	MULTAQ	S	ORAL	800 MG (400 MG,2 IN 1 D),ORAL		
BUNDLE BRANCH BLOCK LEFT	ASPIRIN	C				
	XANAX	C				
	ACIPHEX (RABEPRAZOLE SODIUM)(RABEPRAZOLE SODIUM)	C				
	DABIGATRAN ETEXILATE (DABIGATRAN ETEXILATE) (DABIGATRAN ETEXILATE)	C				
	METOPROLOL SUCCINATE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Nov-2011	8254608	EXPEDITED (15-DAY)	N	OT,RI	1000025257	40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERHIDROSIS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL, 20 MG (20 MG, 1 IN 1 D), ORAL		
CELLULITIS	SYNTHROID (LEVOTHYROZINE SODIUM) (LEVOTHYROXINE SODIUM)	C				
OEDEMA	WELLBUTRIN (BUPROPION HYDROCHLORIDE) (BUPROPION HYDROCHLORIDE)	C				
ARTHRALGIA						
CONSTIPATION						
FLATULENCE						
IRRITABLE BOWEL SYNDROME						
VISION BLURRED						
WEIGHT DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Nov-2011	8245223	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-16219719	27 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	ABILIFY	S	ORAL	Continued in 2006; Stopped and Restarted on 07Oct2011(10-15mg) Also taken 30mg		
HEAD INJURY	ABILIFY	S	ORAL	Continued in 2006; Stopped and Restarted on 07Oct2011(10-15mg) Also taken 30mg		
PSYCHOMOTOR HYPERACTIVITY	LEXAPRO	S		Duration:7years ago		
LOGORRHOEA	LEXAPRO	S		Duration:7years ago		
POLLAKIURIA	GABITRIL	S				
INCREASED APPETITE	GABITRIL	S				
	IBUPROFEN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Nov-2011	8245456	EXPEDITED (15-DAY)	N	HO,OT	PHEH2011US009069		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FALL	LORATADINE	S		10 mg, UNK		NOVARTIS
Balance disorder	GILENYA	S	ORAL	0.5 mg, QD		
DEHYDRATION	NITROFURANTOIN	S		100 mg, BID		
MIGRAINE	LEXAPRO	S		20 mg, QD		
URINARY TRACT INFECTION	LYRICA	S		100 mg, TID		
INFECTION	ADDERALL	S		10 mg, BID		
	AMBIEN	S		5 mg, QD		
	SINGULAIR	S		10 mg, UNK		
	MIRAPEX	S		0.75 mg, (0.25 mg and 0.5 mg)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Nov-2011	8247068	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-16220139		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sjogren's syndrome	ABILIFY	S		Duration of Therapy:About 5 yrs Dose reduced to 2.5mg/D Dose increased to 15mg/D		
AMENORRHOEA	LEXAPRO	S				
ANXIETY						
MENOPAUSAL SYMPTOMS						
SWELLING						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Nov-2011	8258709	EXPEDITED (15-DAY)	N	CA	1000025339	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINA BIFIDA	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
AORTIC STENOSIS						
BICUSPID AORTIC VALVE						
CONGENITAL HYDROCEPHALUS						
Maternal drugs affecting foetus						
PATENT DUCTUS ARTERIOSUS						
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Nov-2011	8258728	EXPEDITED (15-DAY)	N	CA	1000025347	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TALIPES	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
HEART DISEASE CONGENITAL						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Nov-2011	8169158	EXPEDITED (15-DAY)	Y	HO	1000023889	21 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
Intentional overdose	PAXIL	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	CONSTAN (ALPRAZOLAM) (ALPRAZOLAM)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Nov-2011	8264066	EXPEDITED (15-DAY)	Y	OT,RI	1000025502		Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE TWITCHING	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
HEADACHE	ETIZOLAM	S	ORAL	ORAL		
CONFUSIONAL STATE	TANDOSPIRONE (TANDOSPIRONE) (TANDOSPIRONE)	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Nov-2011	8280047	NON-EXPEDITED	N		1000023867	75 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	VIIBRYD	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DIARRHOEA	LEXAPRO	S	ORAL	20 MG, (20 MG, 1 IN 1 D), ORAL		
ABDOMINAL DISTENSION	AMBIEN	S				
ABDOMINAL PAIN	CRESTOR	C				
	GABAPENTIN (GABAPENTIN)	C				
	METFORMIN HYDROCHLORIDE	C				
	LORAZEPAM	C				
	BENICAR	C				
	ENALAPRIL MALEATE	C				
	HYDROCHLOROTHIAZIDE (HYDROCHLOROTHIAZIDE)	C				
	ACETAMINOPHEN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Nov-2011	8192625	EXPEDITED (15-DAY)	Y	OT,RI	1000024486	32 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S		10 MG (10 MG, 1 IN 1 D)		
	AMOXAN (AMOXAPINE) (AMOXAPINE)	C				
	LEXOTAN (BROMAZEPAM) (TABLETS) (BROMAZEPAM)	C				
	FLUNITRAZEPAM (FLUNITRAZEPAM) (FLUNITRAZEPAM)	C				
	IRRIBOW (RAMOSETRON HYDROCHLORIDE) (RAMOSETRON HYDROCHLORIDE)	C				
	BENZALIN (NITRAZEPAM) (NITRAZEPAM)	C				
	RAVONA (PENTOBARBITAL CALCIUM)(PENTOBARBITAL CALCIUM)	C				
	CYMBALTA (DULOXETINE HYDROCHLORIDE)(DULOXETINE HYDROCHLORIDE)	C				
	SENIRAN (BROMAZEPAM) (BROMAZEPAM)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Nov-2011	8268868	EXPEDITED (15-DAY)	Y	OT,RI	1000025531	25 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ALTERED STATE OF CONSCIOUSNESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Nov-2011	8262297	NON-EXPEDITED	Y	OT	US-PFIZER INC-2011283133	16 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EPISTAXIS	REVATIO	S		UNK		PFIZER
	TYVASO	S		216 mcg (54 mcg, 4 in 1 D)		
	LEXAPRO	S		UNK		
	TRACLEER	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Nov-2011	8270838	EXPEDITED (15-DAY)	Y	OT,RI	1000025583	72 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLINDNESS	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Nov-2011	8198861	EXPEDITED (15-DAY)	Y	DE,HO	IE-SANOFI-AVENTIS-2011SA067252	76 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ACUTE HEPATIC FAILURE	RIFADIN	S	ORAL		6 DAY	
HEPATITIS	FUSIDIC ACID	S	ORAL		3 WEEK	
JAUNDICE	METRONIDAZOLE	S	UNKNOWN		3 WEEK	
VOMITING	AUGMENTIN	S	UNKNOWN			
	SEROQUEL	S	ORAL		2 MTH	
	LEXAPRO	S	ORAL		2 MTH	
	ESOMEPRAZOLE	S	ORAL		2 MTH	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Nov-2011	8264238	DIRECT	N	OT		38 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANXIETY	LEXAPRO	S	ORAL	7.5 mg	2 DAY	
GASTROINTESTINAL DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Nov-2011	8264832	EXPEDITED (15-DAY)	N	HO,OT	US-EISAI INC-E3810-05091-SPO-US	82 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LUNG NEOPLASM MALIGNANT	ACIPHEX	S	ORAL			
PRURITUS	LEXAPRO	S	ORAL			
	LEVOTHYROXINE	C	ORAL			
	PINDOLOL	C	ORAL			
	DIOVAN	C	ORAL			
	ZANTAC	C	ORAL			
	PREDNISONE	C	ORAL			
	XANAX	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Nov-2011	8242422	EXPEDITED (15-DAY)	N	OT,RI	1000025057	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BACK PAIN	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
CRYING						
DEPRESSION						
NASAL CONGESTION						
SPEECH DISORDER						
VOMITING						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Nov-2011	8164852	EXPEDITED (15-DAY)	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-16109340	19 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	ABILIFY	S		Started 6 years ago: before 2005		
HEPATIC FAILURE	ABILIFY	S		Started 6 years ago: before 2005		
	LEXAPRO	S		Started 6 years ago		
	LEXAPRO	S		Started 6 years ago		
	TOPAMAX	S				
	IMITREX	C				
	TRAZODONE HYDROCHLORIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Dec-2011	8257397	EXPEDITED (15-DAY)	Y	OT,RI	1000025390	61 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERHIDROSIS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL		
PERIPHERAL COLDNESS	REFLEX (PICOLAMINE SALICYLATE) (PICOLAMINE SALICYLATE)	C				
FEELING HOT	WYPAX (LORAZEPAM) (LORAZEPAM)	C				
CHEST DISCOMFORT						
INSOMNIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Dec-2011	8271866	NON-EXPEDITED			US-PFIZER INC-2011291102		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Weight increased	Pristiq	S		UNK		PFIZER
	Xanax	S		UNK		PFIZER
	ATENOLOL	S		UNK		PFIZER
	ZYPREXA	S		UNK		
	LEXAPRO	S		UNK		
	ZOCOR	S		UNK		
	LEVOTHROID	S		UNK		
	CYMBALTA	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Dec-2011	8283624	EXPEDITED (15-DAY)	Y	OT,RI	1000025218	85 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOPHAGIA	LEXAPRO	S		10 MG (10 MG, 1 IN 1 D)		
HYPOKALAEMIA	MEMANTINE HYDROCHLORIDE	S		10 MG (10 MG, 1 IN 1 D)		
DIARRHOEA	RISPERIDONE (RISPERIDONE)	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Dec-2011	8246297	EXPEDITED (15-DAY)	Y	OT,RI	1000025239	38 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERVENTILATION	LEXAPRO	S		10 MG (10 MG, 1 IN 1 D)		
HYPOAESTHESIA						
INSOMNIA						
LOSS OF CONSCIOUSNESS						
MUSCLE CONTRACTURE						
NAUSEA						
PALPITATIONS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Dec-2011	8282243	DIRECT	Y	OT		11 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION, AUDITORY	LEXAPRO	S	ORAL	5MG HS PO 047		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Dec-2011	8182633	EXPEDITED (15-DAY)	Y	HO,OT	1000024269	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PARAESTHESIA	VIIBRYD	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL, 20 MG (20 MG, 1 IN 1 D),ORAL		
ECZEMA	VIIBRYD	S	ORAL	40 MG (40 MG, 1 IN 1 D),ORAL, 20 MG (20 MG, 1 IN 1 D),ORAL, 10 MG (10 MG, 1 IN 1 D),ORAL		
PANIC ATTACK	LEXAPRO	S				
ABNORMAL DREAMS	ADDERALL (OBETROL)-(OBETROL)	C				
DYSPNOEA	KLONOPIN	C				
ANXIETY						
CONDITION AGGRAVATED						
DEPRESSED MOOD						
INSOMNIA						
MYOCLONUS						
SEROTONIN SYNDROME						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Dec-2011	8292306	EXPEDITED (15-DAY)	N	CA	1000025955	2 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINA BIFIDA	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Dec-2011	8341760	NON-EXPEDITED	N	OT	SPV1-2011-00627	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT DECREASED	ADDERALL	S	ORAL	15 MG, 1X/DAY: QD, ORAL		
	LEXAPRO	S	ORAL	10 MG, 1X/DAY: QD, ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Dec-2011	8261210	NON-EXPEDITED	N	OT	US-PFIZER INC-2011285355	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	ZOLOFT	S	ORAL	25 mg, 1x/day		PFIZER
SOCIAL AVOIDANT BEHAVIOUR	ZOLOFT	S				PFIZER
EMOTIONAL DISORDER	ZOLOFT	S				PFIZER
DRUG INEFFECTIVE	LEXAPRO	S		UNK		
BACK PAIN	CYMBALTA	S		UNK		
	ATIVAN	C		UNK		
	ABILIFY	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Dec-2011	8298304	EXPEDITED (15-DAY)	Y		1000026049	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COUGH	LEXAPRO	S				
ADVERSE EVENT						
SLEEP DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Dec-2011	8285495	NON-EXPEDITED	N		US-PFIZER INC-2011300006		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DECREASED APPETITE	DIFLUCAN	S		UNK		PFIZER
NAUSEA	LEXAPRO	S		5 mg, 1x/day (1 in 1 D)		
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2011	8256730	EXPEDITED (15-DAY)	Y	HO	1000025275	72 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
UVEITIS	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2011	8306548	EXPEDITED (15-DAY)	N	OT,RI	1000025998		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S				
EMOTIONAL DISORDER	ZOLOFT	S				
CRYING	CYMBALTA	S				
CONDITION AGGRAVATED						
DRUG INEFFECTIVE						
SOCIAL AVOIDANT BEHAVIOUR						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8254345	EXPEDITED (15-DAY)	N	OT	AUR-APL-2011-05774	15 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANGER	MIRTAZAPINE (MIRTAZAPINE)	S				
SUICIDAL IDEATION	ZOLOFT	S				
DRUG INEFFECTIVE	SKELAXIN	S				
HEADACHE	EFFEXOR	S		3.75 MG		
FATIGUE	EFFEXOR XR	S				
DISTURBANCE IN ATTENTION	CELEBREX	S				
MOOD ALTERED	GEODON	S				
WEIGHT INCREASED	DEPAKOTE	S				
HEAD INJURY	ZOMIG	S				
MEMORY IMPAIRMENT	IMITREX (SUMATRIPTAN)	S				
RASH	SOMA	S				
SOMNOLENCE	LITHIUM CARBONATE	S				
AGGRESSION	RISPERDAL	S				
AGITATION	SEROQUEL	S				
CONSTIPATION	ZYPREXA	S				
RECTAL HAEMORRHAGE	LEXAPRO	S				
GASTRIC ULCER	LAMICTAL	S				
INFLUENZA	TEGRETOL	S				
INSOMNIA	WELLBUTRIN	S				
ERECTION INCREASED	BUSPAR	S				
DEAFNESS	VALIUM	S				
TINNITUS	TRAZODONE HYDROCHLORIDE	S				
MUSCLE SPASMS	PAXIL	S				
GYNAECOMASTIA	CYMBALTA	S				
	ELAVIL	S				
	KLONOPIN	S				
	RITALIN	S				
	PAMELOR	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8295157	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15478886		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TARDIVE DYSKINESIA	ABILIFY	S	ORAL			
	LAMICTAL	S				
	LEXAPRO	S				
	AMBIEN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8295309	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15867856	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE SPASMS	ABILIFY	S		5mg increased to 10 mg abt 6 months ago	6 MTH	
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8295368	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15512361		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSKINESIA	ABILIFY	S				
	LEXAPRO	S				
	ADDERALL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8295381	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-15878747		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	ABILIFY	S				
	LEXAPRO	S		started with 10 mg, increased to 20mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8295490	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-15896525	22 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BRADYCARDIA	ABILIFY	S	ORAL	restarted on 11Mar2011		
DIZZINESS	ABILIFY	S	ORAL	restarted on 11Mar2011		
FATIGUE	ABILIFY	S	ORAL	restarted on 11Mar2011		
	LEXAPRO	S		10mg On 12Aug10 few weeks Rest 20mg on 11Mar11 Again 30mg 16May11.		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8295571	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15531163		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TARDIVE DYSKINESIA	ABILIFY	S				
	ZOLOFT	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8295617	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15925662	19 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD THYROID STIMULATING HORMONE DECREASED	ABILIFY	S	ORAL	On 23may2011 increased to 15mg		
	LEXAPRO	S				
	WELLBUTRIN	S				
	DEXEDRINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8295670	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15536444	72 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR	ABILIFY	S				
	ALCOHOL	S				
	LEXAPRO	S				
	UNSPECIFIED INGREDIENT	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8295732	NON-EXPEDITED		OT	US-BRISTOL-MYERS SQUIBB COMPANY-15962277	40 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8295735	NON-EXPEDITED	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-15962616	49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CATATONIA	ABILIFY	S		Dose increased:15mg 16Dec2008		
DEPRESSION	LEXAPRO	S		dose reduced to 10 mg		
FALL	KLONOPIN	C		As necessary		
HYPERSENSITIVITY	SPIRONOLACTONE	C				
EXTRAPYRAMIDAL DISORDER	SIMVASTATIN	C				
	AMBIEN CR	C				
	LANOXIN	C				
	CITALOPRAM	C				
	SEROQUEL	C				
	CELEXA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8295822	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-15568058		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PYREXIA	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8295837	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15993371	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OEDEMA	ABILIFY	S				
	ABILIFY	S				
	ABILIFY	S				
	SEROQUEL	S				
	SEROQUEL	S				
	SEROQUEL	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8295928	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15583974	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8296064	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15603087	40 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RESTLESS LEGS SYNDROME	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8296378	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-16172702	46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CRYING	ABILIFY	S		2 tablets at bedtime.		
ABNORMAL BEHAVIOUR	ABILIFY	S		2 tablets at bedtime.		
SCREAMING	LEXAPRO	S				
	DEPAKOTE	S				
	GLYBURIDE	C				
	INSULIN NOS	C				
	LEXAPRO	C				
	CELEXA	C				
	BLOOD PRESSURE MEDICATION	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8296398	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-16189060	27 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE TWITCHING	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8296452	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15659600	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	ABILIFY	S		then increased to 5mg and finally increased to 7.5mg		
	LEXAPRO	S		maximum dose		
	MIRTAZAPINE	S		maximum dose		
	LORAZEPAM	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8296459	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15662539		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	ABILIFY	S				
BLOOD CHOLESTEROL INCREASED	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8296663	NON-EXPEDITED	N	LT,OT	US-BRISTOL-MYERS SQUIBB COMPANY-15697436		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	ABILIFY	S	ORAL			
DRUG INEFFECTIVE	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8296669	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15703317	28 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PREGNANCY	ABILIFY	S	ORAL			
LIVE BIRTH	ABILIFY	S	ORAL			
BREAST FEEDING	ABILIFY	S	ORAL			
SUPPRESSED LACTATION	LEXAPRO	S				
STRESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8296673	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15703598	39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TARDIVE DYSKINESIA	ABILIFY	S			9 MTH	
	LEXAPRO	S			9 MTH	
	RITALIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8296738	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15368665	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SENSATION OF FOREIGN BODY	ABILIFY	S		Initial dose:2mg Dose decreased from 5mg to 2mg		
	TOPAMAX	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8296764	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15375462	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSARTHRIA	ABILIFY	S		Started from 2mg increased to 5 mg		
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8296790	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15721988	62 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABDOMINAL PAIN UPPER	ABILIFY	S				
WEIGHT DECREASED	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8296925	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15750771	73 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OEDEMA PERIPHERAL	ABILIFY	S		Restart with 1 mg daily		
TREMOR	LEXAPRO	S		Initially 10mg given,then 5mg.		
DYSKINESIA	DIAZEPAM	C				
	PREMARIN	C		But not sunday		
	PREDNISONE	C				
	CLONIDINE	C				
	ALBUTEROL SULFATE	C	INHALATION			
	PERCOCET	C		1df=7.5/325mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8297036	NON-EXPEDITED	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-15797848	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	ABILIFY	S		taken as conmed past 3 years		
BLOOD GLUCOSE ABNORMAL	LEXAPRO	S				
WEIGHT INCREASED	DOSTINEX	C			3 YR	
INSOMNIA	QUINAPRIL	C			3 YR	
FATIGUE	REVATIO	C			3 YR	
FOOD CRAVING	DILTIAZEM HYDROCHLORIDE	C			3 YR	
DRUG INEFFECTIVE	RITALIN	C			3 YR	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8297058	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15803414	17 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WEIGHT INCREASED	ABILIFY	S			6 MTH	
	VYVANSE	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2011	8297122	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15432214	78 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSPHONIA	ABILIFY	S	ORAL			
	LEXAPRO	S	ORAL			
	AMLODIPINE	C	ORAL			
	ASPIRIN	C	ORAL			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Dec-2011	8291856	EXPEDITED (15-DAY)	Y	OT,RI	1000025941	48 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PERIPHERAL COLDNESS	LEXAPRO	S	ORAL	10 MG (10 MG , 1 IN 1 D), ORAL		
ANAPHYLACTIC REACTION	DOGMATYL (SULPIRIDE) (TABLETS) (SULIPIRIDE)	C				
DIARRHOEA	MILNACIPRAN HYDROCHLORIDE (MILNACIPRAN HYDROCHLORIDE) (TABLETS) (MILNACIPRAN HYDROCHLORIDE)	C				
FEELING ABNORMAL	WYPAX (LORAZEPAM (TABLETS) (LORAZEPAM)	C				
BLOOD PRESSURE DECREASED	EVAMYL (LORMETAZEPAM) (TABLETS) (LORMETAZEPAM)	C				
	HALCION (TRIAZOLAM) (TABLETS) (TRIAZOLAM)	C				
	LUVOX (FLUVOXAMINE MALEATE) (TABLETS) (FLUVOXAMINE MALEATE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Dec-2011	8300489	EXPEDITED (15-DAY)	Y	HO	US-PFIZER INC-US-WYE-H07238408	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSARTHRIA	DESVENLAFAXINE	S	ORAL	blinded therapy daily	75 DAY	PFIZER
MENTAL STATUS CHANGES	UNSPECIFIED INGREDIENT	S	ORAL	blinded therapy daily	75 DAY	PFIZER
HYPERTENSION	UNSPECIFIED INGREDIENT	S	ORAL	blinded therapy daily	75 DAY	PFIZER
CONDITION AGGRAVATED	DESVENLAFAXINE	S	ORAL	blinded therapy daily	26 DAY	PFIZER
HYPOKALAEMIA	UNSPECIFIED INGREDIENT	S	ORAL	blinded therapy daily	26 DAY	PFIZER
POLYMEDICATION	UNSPECIFIED INGREDIENT	S	ORAL	blinded therapy daily	26 DAY	PFIZER
	IBUPROFEN	S	UNKNOWN	800 mg, 3x/day		PFIZER
	LYRICA	S	UNKNOWN	75 mg, 1x/day		PFIZER
	CLONAZEPAM	S	UNKNOWN	1 mg, 2x/day		
	LORATADINE	S	UNKNOWN	10 mg, 1x/day		PFIZER
	ROBAXIN	S	ORAL	750 mg, 3x/day		PFIZER
	LEXAPRO	S	UNKNOWN	20 mg, 1x/day		
	ABILIFY	S	UNKNOWN	15 mg, 2x/day		
	FLUTICASONE	S	UNKNOWN	2 sprays daily		
	VICODIN	S	UNKNOWN	5/500 PRN		
	ZESTORETIC	S	UNKNOWN	20/12.5 daily		
	AMBIEN	S	ORAL	10 mg, 1x/day		
	VIVELLE	S	TRANSDERMAL	0.1 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Dec-2011	8316107	EXPEDITED (15-DAY)	N	OT,RI	1000026121	69 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	LEXAPRO	S	ORAL	10 MG(10 MG, 1 IN 1 D),ORAL		
OFF LABEL USE						
VOMITING						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Dec-2011	8303058	NON-EXPEDITED	N		US-PFIZER INC-2011306325		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INAPPROPRIATE SCHEDULE OF DRUG ADMINISTRATION	LYRICA	S	ORAL	75 mg, daily		PFIZER
NEURALGIA	LEXAPRO	S		5 mg, UNK		
ANXIETY						
PARAESTHESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Dec-2011	8316995	DIRECT	Y	RI		51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SKIN LESION	LEXAPRO	S		10MG PO QD		
SKIN HYPERPIGMENTATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Dec-2011	8306177	NON-EXPEDITED	N		US-PFIZER INC-2010102880	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INCORRECT DOSE ADMINISTERED	VIAGRA	S	ORAL	UNK		PFIZER
DRUG INTERACTION	NASPRO	C		UNK		
DRUG INEFFECTIVE	NAPROXEN	C		500 mg, daily		
	VITAMIN D	C		UNK		
	VIAGRA	S	ORAL	UNK, as needed		PFIZER
	VIAGRA	S	ORAL	100mg or 150mg, as needed		PFIZER
	VIAGRA	S		100 mg, UNK		PFIZER
	LEXAPRO	S		UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Dec-2011	8343368	EXPEDITED (15-DAY)	N	OT	DSA_48567_2011		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
STRESS	WELLBUTRIN	S		300 MG, BID		
SUICIDAL IDEATION	EFFEXOR	S		DF		
THINKING ABNORMAL	ZYPREXA	S		DF		
	LEXAPRO	S		DF		
	ADDERALL XR	S		DF		
	AMBIEN	S		DF		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2011	8318853	DIRECT	N	HO,DS		36 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DISABILITY	LEXAPRO	S		10 MG A DAY 047		FOREST
WEIGHT DECREASED	GEODON	C				
PERSONALITY CHANGE	PAXIL	C				
PAIN	AMADRYL	C				
INSOMNIA	SEROQUEL	C				
WITHDRAWAL SYNDROME	ACTOS	C				
SOCIAL AVOIDANT BEHAVIOUR	NAPROXIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2011	8322839	EXPEDITED (15-DAY)	Y	OT,RI	1000026475	56 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANGER	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ACTIVATION SYNDROME	ETHYL LOFLAZEPATE	S	ORAL	8 MG (4 MG, 2 IN 1 D), ORAL		
AGITATION	DORAL	C				
AGGRESSION						
BLOOD ALKALINE PHOSPHATASE INCREASED						
BLOOD CHOLESTEROL INCREASED						
BLOOD LACTATE DEHYDROGENASE INCREASED						
PERSONALITY CHANGE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Dec-2011	8325954	DIRECT	Y	OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	PAROXETINE	S	ORAL	30MG 1 DAY PO		CADILA
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10MG 1 DAY PO		
CONFUSIONAL STATE	BENAZEPRIL HCL AND HYDROCHLOROTHIAZIDE	S				
CONDITION AGGRAVATED	PHENERGAN	C				
BLOOD PRESSURE INCREASED	PREMARIN	C				
ANXIETY	DICLOFENAC	C				
INSOMNIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Dec-2011	8315587	EXPEDITED (15-DAY)	Y	OT,RI	1000026247	92 YR	Unknown	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
GASTROOESOPHAGEAL REFLUX DISEASE	RASILEZ (ALISKIREN FUMARATE) (ALISKIREN FUMARATE)	C				
BLOOD PRESSURE SYSTOLIC INCREASED	ARICEPT	C				
ANAEMIA	CARVEDILOL	C				
NO THERAPEUTIC RESPONSE	RISPERDAL	C				
	BUP-4 (PROPIVERINE HYDROCHLORIDE) (PROPIVERINE HYDROCHLORIDE)	C				
	PARIET (RABEPRAZOLE SODIUM) (RABEPRAZOLE SODIUM)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Dec-2011	8327595	EXPEDITED (15-DAY)	Y	OT,RI	1000026509	35 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OPTIC NERVE DISORDER	LEXAPRO	S	ORAL	10-20 MG/DAY, ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2012	8263280	EXPEDITED (15-DAY)		OT	PHEH2011US009343		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD PRESSURE INADEQUATELY CONTROLLED	DIOVAN HCT	S		1 DF, QD		
SCIATICA	DIOVAN HCT	S		1 DF (320/12.5mg), QD		
SLEEP DISORDER	CITALOPRAM	S	ORAL	20 mg, QD		
LIMB DISCOMFORT	OXYCODONE HYDROCHLORIDE	S		5 mg, UNK		
FEELING ABNORMAL	FEXOFENADINE	S		180 mg, QD		
ATROPHY	GABAPENTIN	S		UNK		
MALAISE	MORPHINE	S		30 mg, TID		
HEPATIC ENZYME ABNORMAL	OXYCONTIN	S		30 mg, BID		
NIGHTMARE	CYMBALTA	S		30 mg, QD		
OCULAR DISCOMFORT	CYMBALTA	S		60 mg, QD		
MEMORY IMPAIRMENT	LYRICA	S		25 mg, QD		
ABDOMINAL DISCOMFORT	LEXAPRO	S		10 mg, QD		
MUSCLE SPASMS	EFFEXOR	S		UNK		
ANXIETY	PERCOCET	S		1 DF (5/325mg), UNK		
DRUG INEFFECTIVE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Jan-2012	8318159	NON-EXPEDITED	N		US-PFIZER INC-2011316017	39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AMENORRHOEA	ALDACTONE	S		100 mg, 1x/day (1 in 1 D)		PFIZER
INFLUENZA LIKE ILLNESS	LEXAPRO	S	ORAL	5 mg, 1x/day (1 in 1 D)		
ALOPECIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Jan-2012	8318991	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2011315930	75 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION	PROCARDIA XL	S		UNK		PFIZER
FATIGUE	LEXAPRO	S	ORAL	2.5 mg, 1x/day		
DRUG INEFFECTIVE	LEXAPRO	S	ORAL	5 mg, 1x/day		
DRUG INTERACTION	LEXAPRO	S	ORAL	7.5 mg, 1x/day		
	LEXAPRO	S	ORAL	10 mg, 1x/day		
	LEXAPRO	S	ORAL	15 mg, 1x/day		
	REMERON	S		15 mg, 1x/day	1 DAY	
	PROTONIX	C		UNK		
	MIRALAX	C		UNK		
	VITAMIN D	C		UNK		
	MULTIVITAMINS	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Jan-2012	8333773	EXPEDITED (15-DAY)	N	HO	1000026439	75 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FALL	VIIBRYD	S	ORAL	10 MG (10 MG,1 IN 1 D),ORAL		
HALLUCINATION	LEXAPRO	S	ORAL	2.5 MG (2.5 MG,1 IN 1 D),ORAL ; 5 MG (5 MG, 1 IN 1 D),ORAL ; 7.5 MG (7.5 MG,1 IN 1 D)		
JOINT INJURY	MIRAPEX	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2012	8235024	NON-EXPEDITED	Y	OT	US-PFIZER INC-2011260551	38 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANGIOEDEMA	LISINOPRIL	S		UNK		
DRUG HYPERSENSITIVITY	PENICILLIN	S		UNK		
LIP SWELLING	PRINZIDE	S	ORAL	20-12.5 daily		
SWOLLEN TONGUE	BENADRYL	S		UNK		
	LEXAPRO	S		UNK		
	MOBIC	S		UNK		
	CELEBREX	C		UNK		
	ALLEGRA D-12 HOUR	C		UNK		
	AMOXICILLIN	C		UNK		
	NASONEX	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2012	8257154	EXPEDITED (15-DAY)	Y	OT,RI	1000025384	40 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	DEPROMEL (FLUVOXAMINE)	C				
	CETIRIZINE HYDROCHLORIDE	C				
	LOSARTAN POTASSIUM	C				
	GOODMIN (BRITIZOLAM)	C				
	METOPROLOL TARTRATE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2012	8323921	NON-EXPEDITED	N		US-ABBOTT-11P-163-0705117-00	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	SYNTHROID	S	ORAL			
INSOMNIA	SYNTHROID	S				
ANXIETY	LEXAPRO	S	ORAL			
DYSPNOEA	LORAZEPAM	C				
ALOPECIA						
HYPOTHYROIDISM						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jan-2012	8272276	EXPEDITED (15-DAY)	Y	HO,OT,RI	1000024042	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BIPOLAR I DISORDER	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D), ORAL		
PSYCHOTIC BEHAVIOUR	SEROQUEL	S		300 MG (300 MG,QHS) : 100 MG (100 MG, QAM)		
ASPARTATE AMINOTRANSFERASE INCREASED	ZYPREXA	S				
ALANINE AMINOTRANSFERASE INCREASED	CHANTIX	C				
OVERDOSE	ABILIFY	C				
WEIGHT INCREASED	SAPHRIS (ASENAPINE MALEATE)	C				
PAIN						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jan-2012	7063060	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2009245932	32 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	TRAZODONE HYDROCHLORIDE	S	UNKNOWN			
TOXICITY TO VARIOUS AGENTS	CITALOPRAM	S	UNKNOWN			
	DILANTIN	S	UNKNOWN			PFIZER
	ZYPREXA	S	UNKNOWN	10 mg, 1x/day		
	BENADRYL	S	UNKNOWN			
	SEROQUEL	S	UNKNOWN			
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jan-2012	8326358	NON-EXPEDITED	N		US-PFIZER INC-2012002742	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERTENSION	PRISTIQ EXTENDED RELEASE	S		50 mg, 1x/day		PFIZER
SLEEP DISORDER	PRISTIQ EXTENDED RELEASE	S				PFIZER
DRUG INEFFECTIVE	LIPITOR	S	ORAL	20 mg, 1x/day		PFIZER
ACCIDENT	LORAZEPAM	S		1mg daily		PFIZER
JOINT INJURY	LORAZEPAM	S				PFIZER
	LEXAPRO	S		UNK		
	LUNESTA	S		3mg daily		
	SYNTHROID	S		0.125 mg, 1x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2012	8065721	EXPEDITED (15-DAY)	N	OT,RI	1000022183	49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
TRANSIENT ISCHAEMIC ATTACK	RITONAVIR	S	ORAL	100 MG (100 MG, 1 IN 1 D), ORAL		
	TRUVADA (TENOFOVIR, EMTRICITABINE) (TABLETS) (TENOFOVIR, EMTRICITABINE)	C				
	REYATAZ (ATAZANAVIR SULFATE) (CAPSULES) (ATAZANAVIR SULFATE)	C				
	ALPRAZOLAM (ALPRAZOLAM) (0.5 MILLIGRAM, TABLETS) (ALPRAZOLAM)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2012	8286718	EXPEDITED (15-DAY)	Y	DE	1000025960	< 1 DAY	Unknown	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEATH NEONATAL	LEXAPRO	S	TRANSPLACENTAL	30 MG (30 MG, 1 IN 1 D), TRANSPLACENTAL		
Maternal drugs affecting foetus	ONDANSETRON	C				
	PHENERGAN (PROMETHAZINE) (PROMETHAZINE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2012	8354491	EXPEDITED (15-DAY)	Y	DE	1000026792	60 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC ARREST	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
ELECTROCARDIOGRAM QT PROLONGED	CIPROFLOXACIN	S		(600 MG)		
COLITIS ULCERATIVE	FLUCONAZOLE	S		(200 MG)		
SEPSIS	PIPERACILLIN SODIUM \TAZOBACTAM SODIUM	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jan-2012	8335849	EXPEDITED (15-DAY)	N	HO	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2012-BP-00382BP	75 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION	MIRAPEX	S				BOEHRINGER INGELHEIM
JOINT INJURY	VIIBRYD	S	ORAL	10 mg		
FALL	LEXAPRO	S	ORAL	2.5 mg	2 WEEK	
	LEXAPRO	S	ORAL	5 mg	2 WEEK	
	LEXAPRO	S		7.5 mg	2 WEEK	

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jan-2012	8355783	EXPEDITED (15-DAY)	Y	DE	09-AUR-09644	32 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TOXICITY TO VARIOUS AGENTS	CITALOPRAM HYDROBROMIDE	S		10 MG (10 MG, 1 IN 1 D),		
COMPLETED SUICIDE	ZYPREXA	S				
	SEROQUEL	S				
	BENADRYL	S				
	DILANTIN	S				
	TRAZODONE HYDROCHLORIDE	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Jan-2012	7271875	EXPEDITED (15-DAY)	N	OT	PHHY2010MX04920	78 YR	Male	MEX

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HAEMARTHROSIS	EXELON	S	TRANSDERMAL	1 DF, QD, 1 patch (5 cm2) per day		NOVARTIS
VERTIGO	LEXAPRO	S		UNK UKN, UNK		
SKELETAL INJURY	NORVASC	C		UNK UKN, UNK		
FALL						
GROIN PAIN						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Jan-2012	8339347	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-11P-163-0841251-00	49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TRANSIENT ISCHAEMIC ATTACK	NORVIR	S	ORAL			
DRUG INTERACTION	LEXAPRO	S	ORAL			
	LEXAPRO	S				
	TRUVADA	C	ORAL			
	REYATAZ	C	ORAL			
	ALPRAZOLAM	C	ORAL	Twice a day, as needed		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jan-2012	8281085	EXPEDITED (15-DAY)	Y	HO,OT	US-ASTRAZENECA-2011SE72130	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	SEROQUEL	S	ORAL			
BIPOLAR I DISORDER	SEROQUEL	S	ORAL	100 MG EVERY MORNING, 300 MG EVERY NIGHT		
PAIN	LEXAPRO	S	ORAL			
WEIGHT INCREASED	ZYPREXA	S				
ASPARTATE AMINOTRANSFERASE INCREASED	CHANTIX	C				
ALANINE AMINOTRANSFERASE INCREASED	ABILIFY	C				
	SAPHRIS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jan-2012	8357734	EXPEDITED (15-DAY)	N	OT	DSA_48839_2012	32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
IMPAIRED WORK ABILITY	WELLBUTRIN	S	ORAL	DF ORAL		
ABORTION SPONTANEOUS	LAMICTAL	S	ORAL	300 MG, FREQUENCY UNKNOWN ORAL, DF ORAL		
OVERDOSE	LAMOTRIGINE	S		300 MG OR 400 MG A DAY		
MATERNAL EXPOSURE DURING PREGNANCY	MICROGESTIN 1/20	S		DF		
DEPRESSION	GEODON	S		DF		
CONDITION AGGRAVATED	EFFEXOR	S		DF		
MOVEMENT DISORDER	LEXAPRO	S		DF		
HYPERSOMNIA	LIPITOR	C				
ACTIVITIES OF DAILY LIVING IMPAIRED	TRILEPTAL	C				
DISTURBANCE IN ATTENTION	NORTRIPTYLINE HYDROCHLORIDE	C				
DRUG LEVEL DECREASED	FOLPLEX	C				
STRESS AT WORK	PRENATAL VITAMINS /01549301/	C				
DRUG INEFFECTIVE	FISH OIL	C				
DEPRESSED MOOD						
PREGNANCY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2012	8116486	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2011197848		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	ZOLOFT	S		UNK		PFIZER
RECTAL HAEMORRHAGE	SKELAXIN	S		UNK		PFIZER
DEAFNESS	MIRTAZAPINE	S		UNK		
GASTRIC ULCER	EFFEXOR	S		37.5 mg, UNK		PFIZER
DRUG INEFFECTIVE	EFFEXOR XR	S		UNK		PFIZER
ANGER	CELEBREX	S		UNK		PFIZER

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	GEODON	S		UNK		PFIZER
MOOD SWINGS	DEPAKOTE	S		UNK		
DISTURBANCE IN ATTENTION	ZOMIG	S		UNK		
MEMORY IMPAIRMENT	IMITREX	S		UNK		
WEIGHT INCREASED	SOMA	S		UNK		
RASH	LITHIUM	S		UNK		
AGGRESSION	RISPERDAL	S		UNK		
CONSTIPATION	SEROQUEL	S		UNK		
EAR DISORDER	ZYPREXA	S		UNK		
MUSCLE SPASMS	LEXAPRO	S		UNK		
BREAST ENLARGEMENT	LAMICTAL	S		UNK		
ERECTION INCREASED	TEGRETOL	S		UNK		
INFLUENZA LIKE ILLNESS	WELLBUTRIN	S		UNK		
INSOMNIA	BUSPAR	S		UNK		
DEPENDENCE	VALIUM	S		UNK		
DRUG EFFECT INCREASED	VALIUM	S				
CONDITION AGGRAVATED	VALIUM	S				
UNEVALUABLE EVENT	TRAZODONE HYDROCHLORIDE	S				
AGITATION	TRAZODONE HYDROCHLORIDE	S				
SOMNOLENCE	PAXIL	S		UNK		
FEELING ABNORMAL	CYMBALTA	S				
PAIN	CYMBALTA	S				
ANXIETY	ELAVIL	S		UNK		
	KLONOPIN	S		UNK		
	RITALIN	S				
	PAMELOR	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2012	8343926	EXPEDITED (15-DAY)	N		US-SANOFI-AVENTIS-2011SA002287	90 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANXIETY	LASIX	S	UNKNOWN			
INSOMNIA	LEXAPRO	S	UNKNOWN			
DIZZINESS	DOXAZOSIN MESYLATE	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2012	8353403	DIRECT	Y	HO,LT		25 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ACUTE PSYCHOSIS	LEXAPRO	S	ORAL	10MG DAILY ORAL		FOREST
INSOMNIA	DEPAKOTE	C				
AGITATION	TOPAMAX	C				
CONVERSION DISORDER						
DIET REFUSAL						
DYSKINESIA						
GENERAL PHYSICAL HEALTH DETERIORATION						
HALLUCINATIONS, MIXED						
HYPERSOMNIA						
REFUSAL OF TREATMENT BY PATIENT						
REGRESSIVE BEHAVIOUR						
STEREOTYPY						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2012	8354452	EXPEDITED (15-DAY)	Y	OT,RI	1000026818	65 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABDOMINAL PAIN UPPER	LEXAPRO	S		5 MG (5 MG, 1 IN 1 D)		
NAUSEA	LEXAPRO	S		10 MG (10 MG, 1 IN 1 D)		
RESTLESSNESS	TRAZOLAN (TRAZODONE HYDROCHLORIDE)	C				
CHEST DISCOMFORT	OMEPRAZOL (OMEPRAZOL)	C				
ABASIA						
ANGINA PECTORIS						
HYPOGLYCAEMIA						
PAIN IN EXTREMITY						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2012	8390171	EXPEDITED (15-DAY)	N	CA	1000027180	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL SEPTAL DEFECT	LEXAPRO	S		TRANSPLACENTAL		
CONGENITAL TORTICOLLIS						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2012	8390177	EXPEDITED (15-DAY)	N	CA	1000027181	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL SEPTAL DEFECT	LEXAPRO	S		TRANSPLACENTAL		
Maternal drugs affecting foetus						
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2012	8391062	EXPEDITED (15-DAY)	N	CA	1000027144	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
FALLOT'S TETRALOGY						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Jan-2012	6899368	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009161616	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD PRESSURE INCREASED	LYRICA	S		225 mg		PFIZER
ABDOMINAL PAIN	ATENOLOL	S		25 mg, UNK		PFIZER
DYSPEPSIA	ALTACE	S	ORAL	5 mg, UNK		PFIZER
ABDOMINAL DISTENSION	SIMVASTATIN	S		20 mg		
OEDEMA PERIPHERAL	LEXAPRO	S		20 mg, UNK		
	XYREM	S	ORAL	2 g, 2x/day		
	CYMBALTA	S		60 mg		
	TRIAMTERENE AND HYDROCHLOROTHIAZIDE	C		UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Jan-2012	8336334	EXPEDITED (15-DAY)	Y	HO	1000026336	51 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL, 10 MG (10 MG, 1 IN 1 D), ORAL		
FEELING ABNORMAL	AMOXAN (AMOXAPINE) (AMOXAPINE)	C				
INSOMNIA	DEPAS (ETIZOLAM) (ETIZOLAM)	C				
DECREASED APPETITE	ZOLPIDEM TARTRATE	C				
DEHYDRATION	ROHYPNOL (FLUNITRAZEPAM) (FLUNITRAZEPAM)	C				
ASPARTATE AMINOTRANSFERASE INCREASED						
BLOOD ALBUMIN DECREASED						
BLOOD BILIRUBIN INCREASED						
BLOOD CALCIUM DECREASED						
BLOOD CREATINE PHOSPHOKINASE INCREASED						
BLOOD URIC ACID INCREASED						
CONVULSION						
LYMPHOCYTE PERCENTAGE DECREASED						
WHITE BLOOD CELL COUNT DECREASED						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jan-2012	8353028	EXPEDITED (15-DAY)	N	HO,LT,OT	US-BRISTOL-MYERS SQUIBB COMPANY-16360927	47 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	ABILIFY	S	ORAL	restarted in Jul,Dec11		
MAJOR DEPRESSION	ABILIFY	S	ORAL	restarted in Jul,Dec11		
BLOOD GLUCOSE INCREASED	LEXAPRO	S				
PARANOIA	LEXAPRO	S				
DRUG INEFFECTIVE	WELLBUTRIN	S				
OVERDOSE	WELLBUTRIN	S				
MEDICATION ERROR	PROZAC	S				
HEADACHE	PROZAC	S				
DRY MOUTH	SEROQUEL	C				
DIZZINESS	NEURONTIN	C				
	TOPAMAX	C				
	MISOPROSTOL	C				
	ACTOS	C				
	PRILOSEC	C				
	DIOVAN	C				
	GLIMEPIRIDE	C				
	WELCHOL	C				
	CELEBREX	C				
	VESICARE	C				
	SINGULAIR	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jan-2012	8353701	DIRECT	Y	OT		28 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INSOMNIA	LEXAPRO	S				
ANXIETY						
DEAFNESS						
TINNITUS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2012	8336082	EXPEDITED (15-DAY)	Y	HO,LT	1000026582		Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Intentional overdose	LEXAPRO	S		OVERDOSE: UNCLEAR IF 160MG OR 100 MG (ONCE)		
SUICIDE ATTEMPT	MIRTAZAPINE (MIRTAZAPINE)	S		OVERDOSE 230 MG (ONCE)		
COMA	BACLOFEN	S		OVERDOSE 1850 MG (ONCE)		
BLOOD LACTIC ACID INCREASED						
CONTINUOUS HAEMODIAFILTRATION						
CONVULSION						
MIOSIS						
MUSCLE SPASMS						
POISONING						
RESPIRATORY ACIDOSIS						
SINUS BRADYCARDIA						
SNORING						

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2012	8355689	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2012015409	32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	EFFEXOR	S		UNK		PFIZER
ABORTION SPONTANEOUS	GEODON	S		UNK		PFIZER
DISABILITY	LAMICTAL	S	ORAL	300 mg, UNK		
DEPRESSION	LAMOTRIGINE	S	ORAL	300 mg, UNK		
BEDRIDDEN	MICROGESTIN 1.5/30	S		UNK		
HYPERSOMNIA	WELLBUTRIN	S	ORAL	UNK		
ACTIVITIES OF DAILY LIVING IMPAIRED	LEXAPRO	S		UNK		
DISTURBANCE IN ATTENTION	LIPITOR	C		UNK		
STRESS	TRILEPTAL	C		UNK		
DRUG LEVEL DECREASED	NORTRIPTYLINE	C		UNK		
DEPRESSED MOOD	MULTIVITAMINS	C		UNK		
	PRENATAL VITAMINS	C		UNK		
	FISH OIL	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2012	8356098	DIRECT	N	HO,OT		27 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR	LEXAPRO	S	ORAL	1 tab		
BLINDNESS						
MENTAL IMPAIRMENT						
MIGRAINE						
SPEECH DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2012	8382052	EXPEDITED (15-DAY)	Y	LT,OT,RI	1000026517	35 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEADACHE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL		
BRADYCARDIA	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D),ORAL		
FALL	DRUG FOR HEADACHE (DRUG FOR HEADACHE) (DRUG FOR HEADACHE)	C				
LOSS OF CONSCIOUSNESS	DOGMATYL (SULPIRIDE) (SULPIRIDE)	C				
AMNESIA	WYPAX (LORAZEPAM) (LORAZEPAM)	C				
ASTHENIA	ZOLPIDEM TARTRATE	C				
PAROSMIA	DEPAS (ETIZOLAM) (ETIZOLAM)	C				
COUGH	LEXOTAN (BROMAZEPAM) (BROMAZEPAM)	C				
TIC	ASMEDIN (CIMETIDINE) (DIMETIDINE)	C				
	KIPRES (MONTELUKAST SODIUM) (MONTELUKAST SODIUM)	C				
	LANSOPRAZOLE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2012	8357867	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0914299A	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ERECTILE DYSFUNCTION	WELLBUTRIN XL	S	ORAL	300MG Per day		GLAXOSMITHKLINE
	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2012	8357909	NON-EXPEDITED	Y		US-GLAXOSMITHKLINE-A0928630A	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSPEPSIA	WELLBUTRIN	S	ORAL	160MG Per day	28 DAY	GLAXOSMITHKLINE
GASTROOESOPHAGEAL REFLUX DISEASE	LEXAPRO	S	ORAL	10MG Per day	26 DAY	
SENSATION OF FOREIGN BODY	LEXAPRO	S	ORAL	5MG Per day	4 DAY	
BACK PAIN						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2012	8360108	NON-EXPEDITED	Y	OT	US-GLAXOSMITHKLINE-A0903029A	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	WELLBUTRIN	S	UNKNOWN			GLAXOSMITHKLINE
OEDEMA PERIPHERAL	SAPHRIS	S	SUBLINGUAL	20MG At night		
INAPPROPRIATE SCHEDULE OF DRUG ADMINISTRATION	LEXAPRO	S	UNKNOWN			
	ALPRAZOLAM	C		4MG At night		GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2012	8394695	EXPEDITED (15-DAY)	Y	DE,CA	1000027276		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINA BIFIDA	LEXAPRO	S	TRANSPLACENTAL	20 MG (20 MG,1 IN 1 D), TRANSPLACENTAL		
ABORTION INDUCED						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2012	8394696	EXPEDITED (15-DAY)	N	CA	1000027413	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CRANIOSYNOSTOSIS	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2012	8396430	EXPEDITED (15-DAY)	Y	HO	1000027402	< 1 DAY	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NEONATAL RESPIRATORY DEPRESSION	LEXAPRO	S	TRANSPLACENTAL	20 MG (20 MG,1 IN 1 D), TRANSPLACENTAL		
Maternal drugs affecting foetus	FERROFUMARAAT (FERROUS FUMARATE)	C				
	OMEPRAZOLE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2012	8378738	NON-EXPEDITED	N		US-ABBOTT-11P-163-0860738-00	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALOPECIA	HUMIRA	S	SUBCUTANEOUS			
	LEXAPRO	S		20 mg tablet daily		
	SIMVASTATIN	C				
	FENOFIBRATE	C				
	LEVOTHYROXINE	C				
	LEXAPRO	C				
	NEOCON	C		0.5-35-28 daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2012	8324463	NON-EXPEDITED	Y		US-PFIZER INC-2012002012		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG HYPERSENSITIVITY	NEURONTIN	S	ORAL	300 mg, 1x/day	11 DAY	PFIZER
NAUSEA	LEXAPRO	S		UNK		
DIZZINESS	VERSED	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2012	8339776	EXPEDITED (15-DAY)		OT	PHHY2012US002247	78 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LIVER INJURY	DICLOFENAC	S		UNK UKN, UNK		NOVARTIS
HEPATITIS	NITROFURANTOIN	S		UNK UKN, UNK		
	LEXAPRO	S		10 mg, QD		
	LEXAPRO	S		20 mg, QD		
	LISINOPRIL	C		UNK UKN, UNK		
	FUROSEMIDE	C		UNK UKN, UNK		
	LORATADINE	C		UNK UKN, UNK		
	CYMBALTA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2012	8347928	NON-EXPEDITED	Y		US-PFIZER INC-2012013038		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	PRISTIQ EXTENDED RELEASE	S		50 mg, 1x/day		PFIZER
	LORAZEPAM	S		0.5 mg, 2x/day		PFIZER
	PROZAC	S		30 mg, UNK	91 DAY	
	LEXAPRO	S		20 mg, UNK	91 DAY	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Jan-2012	8373108	NON-EXPEDITED	Y	OT	US-PFIZER INC-2012021057		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEROTONIN SYNDROME	ZYVOX	S		UNK		PFIZER
DISORIENTATION	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Jan-2012	8391211	EXPEDITED (15-DAY)	N	OT	AUR-APL-2012-00505	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSPEPSIA	ATENOLOL (ATENOLOL)	S		(25 MG), UNKNOWN		
ABDOMINAL PAIN	SIMVASTATIN	S		(20 MG), UNKNOWN		
ABDOMINAL DISTENSION	LYRICA	S		(225 MG), UNKNOWN		
BLOOD PRESSURE INCREASED	ALTACE	S	ORAL	(5 MG), ORAL		
OEDEMA PERIPHERAL	LEXAPRO	S		(20 MG), UNKNOWN		
JOINT SWELLING	XYREM	S	ORAL	4 GM (2 GM, 2 IN 1 D), ORAL		
	CYMBALTA	S		(60 MG), UNKNOWN		
	DYAZIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Feb-2012	8382506	EXPEDITED (15-DAY)	N	OT	US-WATSON-2012-00582	32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DISABILITY	MICROGESTIN FE 1.5/30	S	UNKNOWN	UNK		WATSON
ABORTION SPONTANEOUS	LAMICTAL	S	ORAL	300 mg		
OVERDOSE	LAMOTRIGINE	S	ORAL	300 mg		
DEPRESSION	ZIPRASIDONE HYDROCHLORIDE	S	UNKNOWN	UNK		
BEDRIDDEN	WELLBUTRIN XL	S	ORAL	UNK		
HYPERSOMNIA	VENLAFAXINE	S	UNKNOWN	UNK		
ACTIVITIES OF DAILY LIVING IMPAIRED	LEXAPRO	S	UNKNOWN	UNK		
DISTURBANCE IN ATTENTION	ATORVASTATIN CALCIUM	C	UNKNOWN	UNK		
STRESS	OXCARBAZEPINE	C	UNKNOWN	UNK		
MATERNAL EXPOSURE DURING PREGNANCY	NORTRIPTYLINE HYDROCHLORIDE	C	UNKNOWN	UNK		
DRUG LEVEL DECREASED	CYANOCOBALAMIN\FOLIC ACID \PYRIDOXINE HYDROCHLORIDE	C	UNKNOWN	UNK		
	ASCORBIC ACID\BIOTIN\RETINOL \TOCOPHEROL	C	UNKNOWN	UNK		
	FISH OIL	C	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Feb-2012	8399982	EXPEDITED (15-DAY)	N	OT,RI	1000027356	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MIGRAINE	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
HEART RATE INCREASED	FENTANYL CITRATE	C				
PALPITATIONS	SOMA	C				
DYSPNOEA	NORCO (HYDROCODONE, ACETAMINOPHEN)	C				
	TRAZODONE HYDROCHLORIDE	C				
	GABAPENTIN	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2012	8314830	EXPEDITED (15-DAY)	N	OT,RI	1000026217	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NEOPLASM MALIGNANT	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL		
CONDITION AGGRAVATED	LEXAPRO	S	ORAL	20 MG (20 MG,1 IN 1 D),ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2012	8388007	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0903725A	65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LAMICTAL	S	ORAL			GLAXOSMITHKLINE
DIARRHOEA	LEXAPRO	S	ORAL	5MG Per day		
DIZZINESS	IMODIUM	S	ORAL			
BLOOD PRESSURE INCREASED						
FLUSHING						
HEADACHE						
MALAISE						
NAUSEA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2012	8394899	DIRECT	N	HO,DS			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PANIC ATTACK	CITALOPRAM HYDROBROMIDE	S	ORAL	CITALOPRAM 20 MG DAILY BY MOUTH		
AKATHISIA	LEXAPRO	S	ORAL	LEXAPRO 10 MG DAILY BY MOUTH		FOREST
DISTURBANCE IN ATTENTION						
DYSKINESIA						
INAPPROPRIATE AFFECT						
LOGORRHOEA						
MEMORY IMPAIRMENT						
MENTAL STATUS CHANGES						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2012	8395431	DIRECT	Y			19 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TRISMUS	LEXAPRO	S	ORAL	LEXAPRO 5MG 1 UP TO 2QD PO STARTING DOSE		FOREST
	LEXAPRO	S	ORAL	LEXAPRO 20MG 1QD PO		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2012	8406467	EXPEDITED (15-DAY)	Y	OT	1000027417	69 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EYE HAEMORRHAGE	LEXAPRO	S	ORAL	15 MG (15 MG,1 IN 1 D),ORAL		
	DILANTIN	C				
	NEURONTIN	C				
	AVALIDE (KARVEA HCT) (KARVEA HCT)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2012	8406480	EXPEDITED (15-DAY)	N	CA	1000027562	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOPLASTIC LEFT HEART SYNDROME	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Congenital aortic stenosis						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2012	8406555	EXPEDITED (15-DAY)	Y		1000027384		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANORGASMIA	LEXAPRO	S				
	ADDERALL	S				
	DEXILANT	S				
	ZETIA	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Feb-2012	8200520	EXPEDITED (15-DAY)	Y	OT,RI	1000024586		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal drugs affecting foetus	LEXAPRO	S		20 MG (20 MG, 1 IN 1),		
CAESAREAN SECTION						
SUPRAVENTRICULAR EXTRASYSTOLES						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Feb-2012	8393837	DIRECT	N	DS		43 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AKATHISIA	PROZAC	S	ORAL	1-2 per day		
QUALITY OF LIFE DECREASED	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Feb-2012	8412485	EXPEDITED (15-DAY)	Y	OT,RI	1000027592	57 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONFUSIONAL STATE	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
SYNCOPE	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
	THYROX (LEVOTHYROXINE SODIUM) (LEVOTHYROXINE SODIUM)	C				
	ANASTROZOL (ANASTROZOLE) (ANASTROZOLE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Feb-2012	8356822	EXPEDITED (15-DAY)	Y	HO	JP-ABBOTT-12P-087-0897995-00	77 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPONATRAEMIA	BIPERIDEN HYDROCHLORIDE	S	ORAL	(3 milligrams)		
URINARY RETENTION	LEXAPRO	S		(10 milligrams)		
HALLUCINATION, VISUAL	ANTIHYPERTENSIVES	C				
CONFUSIONAL STATE	HYPNOTICS AND SEDATIVES	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Feb-2012	8395356	DIRECT	N	LT		57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGITATION	LEXAPRO	S	ORAL	10 mg	4 DAY	
PANIC REACTION						
SEROTONIN SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Feb-2012	8396517	NON-EXPEDITED	N		US-PFIZER INC-2012030008		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	ZOLOFT	S		UNK		PFIZER
	EFFEXOR XR	S		UNK		PFIZER
	PROZAC	S		UNK		
	CELEXA	S		UNK		
	LEXAPRO	S		UNK		
	WELLBUTRIN	S		UNK		
	CYMBALTA	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2012	8399749	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0945641A		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NIGHT SWEATS	PAXIL	S	UNKNOWN	40MG per day		GLAXOSMITHKLINE
MIDDLE INSOMNIA	LEXAPRO	S	UNKNOWN			
ABDOMINAL PAIN UPPER						
ATTENTION DEFICIT/HYPERACTIVITY DISORDER						
HYPERHIDROSIS						
LIBIDO DECREASED						
LOSS OF LIBIDO						
POST-TRAUMATIC STRESS DISORDER						
SOMNOLENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2012	8399843	NON-EXPEDITED	Y		US-GLAXOSMITHKLINE-A0957158A		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WITHDRAWAL SYNDROME	PAXIL CR	S	ORAL	12.5MG Per day		GLAXOSMITHKLINE
PALPITATIONS	LEXAPRO	S	ORAL			
ANXIETY						
BLOOD CORTISOL INCREASED						
GASTRITIS EROSIVE						
INSOMNIA						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2012	8422602	EXPEDITED (15-DAY)	Y	DS	1000028049	21 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OVERDOSE	LEXAPRO	S	ORAL	OVERDOSE: 10 - 30 MG A DAY (10 MG), ORAL		
ATONIC URINARY BLADDER						
URINARY RETENTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2012	8422684	EXPEDITED (15-DAY)	Y	CA	1000027920	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOPLASTIC LEFT HEART SYNDROME	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2012	8422708	EXPEDITED (15-DAY)	N	CA	1000027890	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FALLOT'S TETRALOGY	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2012	8422365	EXPEDITED (15-DAY)	N	CA	1000028169	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
COARCTATION OF THE AORTA						
Maternal drugs affecting foetus						
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2012	8422417	EXPEDITED (15-DAY)	N	CA	1000028153	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINA BIFIDA	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
ARNOLD-CHIARI MALFORMATION						
CEREBRAL VENTRICLE DILATATION						
CONGENITAL HYDROCEPHALUS						
Maternal drugs affecting foetus						
MICROCEPHALY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2012	8422429	EXPEDITED (15-DAY)	N	CA	1000028145	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONGENITAL TRICUSPID VALVE ATRESIA	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
FOETAL EXPOSURE DURING PREGNANCY						
PULMONARY ARTERY STENOSIS CONGENITAL						
TRANSPOSITION OF THE GREAT VESSELS						
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2012	8422438	EXPEDITED (15-DAY)	N	CA	1000028143	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
DOUBLE OUTLET RIGHT VENTRICLE						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2012	8422449	EXPEDITED (15-DAY)	N	CA	1000028138	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ARNOLD-CHIARI MALFORMATION	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
FOETAL EXPOSURE DURING PREGNANCY						
SPINA BIFIDA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2012	8422458	EXPEDITED (15-DAY)	N	CA	1000028126	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL	TRANSLACENTAL		
Maternal drugs affecting foetus						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2012	8451364	NON-EXPEDITED	N		1000026361		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INSOMNIA	SAVELLA	S	ORAL	12.5 MG (12.5 MG, 1 IN 1 D), ORAL		
ENERGY INCREASED	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
DRUG INEFFECTIVE	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
ABNORMAL DREAMS						
CRYING						
OFF LABEL USE						

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Feb-2012	8431655	EXPEDITED (15-DAY)	Y	LT,OT,RI	1000028093	< 1 DAY	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NEONATAL ASPHYXIA	LEXAPRO	S		10 MG (10 MG, 1 IN 1 D),TRANSPLACENTAL ; 20 MG (20 MG, 1 IN 1 D),TRANSPLACENTAL		
CONVULSION NEONATAL	ZOLOFT (SERTRALINE HYDROCHLORIDE) (SETRALINE HYDROCHLORIDE)	C				
CAESAREAN SECTION	REFLEX (MIRTAZAPINE) (MIRTAZAPINE)	C				
Maternal drugs affecting foetus	HALRACK (TRIAZOLAM) (TRIAZOLAM)	C				
	SILECE (FLUNITRAZEPAM) (FLUNITRAZEPAM)	C				
	LEVOTOMIN (LEVOMEPROMAZINE MALEATE) (LEVOMEPROMAZINE MALEATE)	C				
	SOLANAX (ALPRAZOLAM) (ALPRAZOLAM)	C				
	LEXOTAN (BROMAZEPAM) (BROMAZEPAM)	C				
	RISPERIDONE	C				
	LEKRICA (CHLORPHENAMINE MALEATE) (CHLORPHENAMINE MALEATE)	C				
	GOODMIN (BROTIZOLAM) (BROTIZOLAM)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2012	8286481	EXPEDITED (15-DAY)	Y	OT,RI	1000025959	33 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PREMATURE DELIVERY	LEXAPRO	S	ORAL	30 MG (30 MG, 1 IN 1 D), ORAL		
OVERDOSE	ONDANSETRON	C				
PREGNANCY	PHENERGAN	C				
MATERNAL EXPOSURE DURING PREGNANCY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2012	8402564	EXPEDITED (15-DAY)	Y	HO	1000027473	24 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
ACTIVATION SYNDROME	RISPERIDONE (RISPERIDONE)	C				
DEPRESSION SUICIDAL	TEFMETIN (TRIMEBUTINE MALEATE)	C				
NAUSEA						
PYREXIA						
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2012	8410860	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2012039637	32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug interaction	Dilantin-125	S		UNK		PFIZER
Convulsion	SUMATRIPTAN SUCCINATE	S	INTRAMENINGEAL	6 mg, UNK		
Myocardial infarction	LEXAPRO	S	ORAL	20 mg, 1x/day		
Throat tightness	SUMATRIPTAN	S		50 mg, UNK		
Dyspnoea	ZONEGRAN	C		UNK		
Chest discomfort	NEURONTIN	C		UNK		
Pruritus generalised	TEMAZEPAM	C		UNK		
Tremor	FAMOTIDINE	C		UNK		
Nausea	MULTIVITAMINS	C		UNK		
Dry mouth						
Feeling abnormal						
Oral discomfort						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2012	8411312	EXPEDITED (15-DAY)	N	DS,OT	US-JNJFOC-20120205160		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EPILEPSY	TOPAMAX	S	ORAL	100 mg 1 tablet in the morning and 2 tablets at night		
DRUG INTERACTION	PROVERA	S	ORAL			
SOMNOLENCE	PREMARIN	S	ORAL			
TREMOR	LAMICTAL	S	ORAL			
Balance disorder	VIMPAT	S	UNKNOWN			
DRUG INEFFECTIVE	LEXAPRO	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Feb-2012	8435299	EXPEDITED (15-DAY)	N	DS,OT,RI	1000028218	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EPILEPSY	LEXAPRO	S		20 MG (20 MG, 1 IN 1 D)		
Balance disorder	PROVERA	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL, 20 YEARS AGO		
TREMOR	PREMARIN	S	ORAL	0.625 MG (0.625 MG, 1 IN 1 D), ORAL		
DRUG INTERACTION	LAMICTAL	S	ORAL	300 MG (150 MG, 2 IN 1 D), ORAL		
SOMNOLENCE	TOPAMAX	S	ORAL	300 MG (100 MG QAM AND 200 MG QPM),ORAL		
DRUG INEFFECTIVE	VIMPAT	S	ORAL	400 MG (100 MG, 4 IN 1 D),ORAL		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Feb-2012	8436943	EXPEDITED (15-DAY)	N	CA	1000028280		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CLEFT PALATE	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL, 7.5 MG (7.5 MG, 1 IN 1 D), ORAL		

Maternal drugs affecting foetus

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Feb-2012	8454632	NON-EXPEDITED	N		1000025781	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONTUSION	VIIBRYD	S	ORAL	10 MG (10 MG, 1 I N1 D), ORAL, 20 MG (20 MG, 1 IN 1 D), ORAL		
CYSTITIS	VIIBRYD	S	ORAL	30 MG (30 MG, 1 IN 1 D), ORAL, 20 MG (20 MG, 1 IN 1 D), ORAL		
INSOMNIA	LEXAPRO	S				
OFF LABEL USE	VYVANSE (LISDEXAMFETAMINE MESILATE) (LISDEXAMFETAMINE MESILATE)	C				
	SIMVASTATIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Feb-2012	8382082	EXPEDITED (15-DAY)	Y	OT,RI	1000027107	43 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEPATIC FUNCTION ABNORMAL	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
BLOOD LACTATE DEHYDROGENASE INCREASED	REFLEX (MIRTAZAPINE) (MIRTAZAPINE)	C				
GAMMA-GLUTAMYLTRANSFERASE	GASCON (DIMETICONE) (DIMETICONE)	C				
ASPARTATE AMINOTRANSFERASE INCREASED	GASMOTIN (MOSAPRIDE CITRATE) (MOSAPRIDE CITRATE)	C				
ALANINE AMINOTRANSFERASE INCREASED	MAGMITT (MAGNESIUM OXIDE) (MAGNESIUM OXIDE)	C				
	LORAZEPAM	C				
	ROHYPHNOL (FLUNITRAZEPAM) (FLUNITRAZEPAM)	C				
	RISPERDAL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Feb-2012	8420895	DIRECT	N	OT		39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOAESTHESIA	LEXAPRO	S				
ANHEDONIA						
ANORGASMIA						
DEPERSONALISATION						
EMOTIONAL DISORDER						
LIBIDO DECREASED						
MATERNAL EXPOSURE BEFORE PREGNANCY						
PERSONALITY CHANGE						
PREGNANCY						
SEXUAL DYSFUNCTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2012	8431325	EXPEDITED (15-DAY)	Y	HO	1000028239	84 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIZZINESS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D),ORAL		
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D),ORAL		
CONVULSION	RHEUMATREX (METHOTREXATE) (METHOTREXATE)	C				
LOSS OF CONSCIOUSNESS	REMICADE	C				
	DUROTEP (FENTANYL) (FENTANYL)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2012	8444571	EXPEDITED (15-DAY)	Y	HO,OT,RI	1000028452		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ACUTE PSYCHOSIS	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
INSOMNIA	LEXAPRO	S	ORAL	5 MG (5 MG, 1 IN 1 D), ORAL		
AGITATION	DEPAKOTE	C				
HALLUCINATION, AUDITORY	TOPAMAX (TOPIRAMATE) (TOPIRAMATE)	C				
CONVERSION DISORDER	LEVOTHYROXINE (LEVOTHYROXINE SODIUM) (LEVOTHYROXINE SODIUM)	C				
DYSKINESIA						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2012	8423864	NON-EXPEDITED	N		US-MYLANLABS-2011S1026036	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
THROAT TIGHTNESS	LEXAPRO	S				MYLAN
FEELING ABNORMAL	UNSPECIFIED INGREDIENT	S				
	PERPHENAZINE	S				
	ALPRAZOLAM	S				MYLAN

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2012	8424706	NON-EXPEDITED	N		US-PFIZER INC-K201100732	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANGIOEDEMA	ALTACE	S		UNK		PFIZER
DIZZINESS	LEXAPRO	S	ORAL	5 mg, 1x/day		
	LEXAPRO	S	ORAL	10 mg, 1x/day		
	LEXAPRO	S	ORAL	20 mg, 1x/day		
	BETA BLOCKING AGENTS	C		25 mg, UNK		
	FOLIC ACID	C		UNK		
	NIASPAN	C		1 g, UNK		
	ASPIRIN	C		UNK		
	PRILOSEC	C		UNK		
	B50	C		UNK		
	UBIDECARENONE	C		200 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2012	8436024	EXPEDITED (15-DAY)	Y	HO	1000028442	65 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	LEXAPRO	S	ORAL	20 MG (10 MG, 1 IN 2 D), ORAL		
LOSS OF CONSCIOUSNESS	DOGMATYL (SULPIRIDE (SULPIRIDE)	C				
	ANAFRANIL	C				
	CYMBALTA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2012	8436881	EXPEDITED (15-DAY)	Y	HO	1000028406	59 YR	Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ALANINE AMINOTRANSFERASE INCREASED	LEXAPRO	S	ORAL	10;20 MG (10;20 MG, 1 IN 1 D), ORAL		
LIVER DISORDER	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
CONDITION AGGRAVATED	RISPERDAL	S	ORAL	1;0.5 ML (1;0.5 ML, 1 IN 1 D), ORAL		
ASPARTATE AMINOTRANSFERASE INCREASED	GASMOTIN (MOSAPRIDE CITRATE)	C				
BLOOD LACTATE DEHYDROGENASE INCREASED	ENSURE LIQUID (ENSURE / 06184901/)	C				
GAMMA-GLUTAMYLTRANSFERASE INCREASED	JZOLOFT (SETRTRALINE HYDROCHLORIDE)	C				
	MAGMITT (MAGNESIUM OXIDE)	C				
	SENNOSIDE (SENNOSIDE A+B)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2012	8441365	EXPEDITED (15-DAY)	Y	OT,RI	1000028513		Female	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INTENTIONAL SELF-INJURY	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
AMENORRHOEA						
DIZZINESS						
MEMORY IMPAIRMENT						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2012	8443536	EXPEDITED (15-DAY)	N	CA	1000028595	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TALIPES	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
FOETAL EXPOSURE DURING PREGNANCY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2012	8443550	EXPEDITED (15-DAY)		CA	1000028598	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINA BIFIDA	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2012	8443556	EXPEDITED (15-DAY)	N	CA	1000028593	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CLEFT LIP AND PALATE	LEXAPRO	S	TRANSPLACENTAL	TRANSPLACENTAL		
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2012	8445074	EXPEDITED (15-DAY)	Y	OT,RI	1000028545	52 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME	LEXAPRO	S	ORAL	10 MG (10 MG, 1 IN 1 D), ORAL		
AGITATION	LANSOPRAZOLE	C				
ERECTILE DYSFUNCTION						
PARAESTHESIA						
TREMOR						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Feb-2012	8444005	EXPEDITED (15-DAY)	Y	OT,RI	1000028582	33 YR	Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLOOD TRIGLYCERIDES INCREASED	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D),ORAL		
	MEILAX (ETHYL LOFLAZEPATE) (ETHYL LOFLAZEPATE)	C				
	FLUNITRAZEPAM (FLUNITRAZEPAM) (FLUNITRAZEPAM)	C				
	ABILIFY(ARIPIPRAZOLE) (ARIPIPRAZOLE)	C				
	LANSOPRAZOLE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Feb-2012	8444267	EXPEDITED (15-DAY)	Y	OT,RI	1000028492	24 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	VIIBRYD	S				
INTENTIONAL OVERDOSE	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Feb-2012	8432205	DIRECT		HO		29 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	LEXAPRO	S	ORAL	250 mg		
DIABETES MELLITUS	VITAMINS	C				
CARDIAC VALVE DISEASE						
NAUSEA						
NIGHTMARE						
NIGHT SWEATS						
SUICIDAL IDEATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Feb-2012	8432641	NON-EXPEDITED	Y		US-PFIZER INC-2012051184		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG HYPERSENSITIVITY	CARDURA	S		UNK		PFIZER
	AMOXICILLIN	S		UNK		PFIZER
	ZOLOFT	S		UNK		PFIZER
	SULFASALAZINE	S		UNK		PFIZER
	LEXAPRO	S		UNK		
	SYMBYAX	S		UNK		
	LOTENSIN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Feb-2012	8433188	EXPEDITED (15-DAY)	N	CA	US-FRI-1000028138	33 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINA BIFIDA	LEXAPRO	S	TRANSPLACENTAL			
ARNOLD-CHIARI MALFORMATION	FOLIC ACID	C	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Feb-2012	8433928	EXPEDITED (15-DAY)	N	HO	US-FRI-1000028168	30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MATERNAL EXPOSURE DURING PREGNANCY	LEXAPRO	S	ORAL	10 MG		
PREMATURE RUPTURE OF MEMBRANES	LEXAPRO	S				
DYSPNOEA	ALLEGRA	C				
CHEST PAIN	BUSPAR	C				
SINUS TACHYCARDIA	SKELAXIN	C				
ELECTROCARDIOGRAM ST SEGMENT ABNORMAL	IMITREX	C				
LIMB DISCOMFORT	ORTHO CYCLEN	C				
BACK PAIN	ATIVAN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Feb-2012	8441366	DIRECT	N	OT		55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	LEXAPRO	S		10MGS ONCE DAILY 7 DAYS		FOREST
TREMOR	LEXAPRO	S				
DIZZINESS						
DRUG INEFFECTIVE						
MIGRAINE						
RASH						
RENAL PAIN						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Mar-2012	8434787	EXPEDITED (15-DAY)	N	CA	US-FRI-1000028280		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CLEFT PALATE	LEXAPRO	S	TRANSPLACENTAL	5 MG		
	LEXAPRO	S	TRANSPLACENTAL	7.5 MG		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Mar-2012	8435106	EXPEDITED (15-DAY)	N	CA,OT	US-FRI-1000028143		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			
DOUBLE OUTLET RIGHT VENTRICLE	PRENATABS FA	C	TRANSPLACENTAL			
PYELOCALIECTASIS	AMOXICILLIN	C	TRANSPLACENTAL			
TRANSPOSITION OF THE GREAT VESSELS	FOLIC ACID	C	TRANSPLACENTAL			
VENTRICULAR EXTRASYSTOLES	VITAMIN B12	C	TRANSPLACENTAL			
	VITAMIN C	C	TRANSPLACENTAL			
	FERROUS SULFATE	C	TRANSPLACENTAL			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2012	8354946	EXPEDITED (15-DAY)	Y	DS,OT	US-PFIZER INC-2012017345		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EPILEPSY	PROVERA	S	ORAL	10 mg, daily		PFIZER
Balance disorder	PREMARIN	S	ORAL	0.625 mg, daily		PFIZER
TREMOR	LAMICTAL	S	ORAL	150 mg, 2x/day		
SOMNOLENCE	TOPAMAX	S	ORAL	UNK,2x/day		
DRUG INTERACTION	LACOSAMIDE	S		100 mg, 4x/day		
DRUG INEFFECTIVE	LEXAPRO	S		20 mg, daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2012	8437664	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000027107	43 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEPATIC FUNCTION ABNORMAL	LEXAPRO	S	ORAL	20 mg		
	MIRTAZAPINE	C	ORAL	15 mg		
	GASCON	C	ORAL	120 mg		
	MOSAPRIDE CITRATE	C	ORAL	15 mg		
	MAGNESIUM OXIDE	C	ORAL	750 mg		
	LORAZEPAM	C	ORAL	1.5 mg		
	FLUNITRAZEPAM	C	ORAL	2 mg		
	RISPERDAL	C	ORAL	1 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2012	8438400	EXPEDITED (15-DAY)	N	OT	US-FRI-1000027356	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEART RATE INCREASED	LEXAPRO	S	ORAL	20 mg		
PALPITATIONS	FENTANYL	C				
DYSPNOEA	SOMA	C				
MIGRAINE	NORCO	C				
	TRAZODONE HYDROCHLORIDE	C				
	GABAPENTIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2012	8438429	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2012052996	48 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	PRISTIQ EXTENDED RELEASE	S		50 mg, daily		PFIZER
MOOD SWINGS	WELLBUTRIN	S		UNK		
PARANOIA	LEXAPRO	S		UNK		
INSOMNIA	SEROQUEL	S		300 mg, daily		
	SEROQUEL	S		600 mg daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2012	8438619	EXPEDITED (15-DAY)	N	OT	US-FRI-1000028633		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING ABNORMAL	LEXAPRO	S	ORAL	10 mg		
DYSKINESIA						
FALL						
MOVEMENT DISORDER						
MUSCLE TWITCHING						
PARAESTHESIA						
VISUAL IMPAIRMENT						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2012	8438787	NON-EXPEDITED	N		US-PFIZER INC-2012049389		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG HYPERSENSITIVITY	IBUPROFEN	S		UNK		PFIZER
	ZOLOFT	S		UNK		PFIZER
	OXYCODONE HYDROCHLORIDE	S		UNK		PFIZER
	PREDNISONE	S		UNK		
	CIPRO	S		UNK		
	HYDROCODONE	S		UNK		
	LEXAPRO	S		UNK		
	BACTRIM	S		UNK		
	ZETIA	S		UNK		
	PERCOCET	S		UNK		
	TYLOX	S		UNK		
	REGLAN	S		UNK		
	DEMEROL	S		UNK		
	DARVOCET-N	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2012	8442601	DIRECT	N	DS,OT		47 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	LEXAPRO	S	ORAL	10 MG, 1 a day, po		
DEPRESSION						
DISEASE RECURRENCE						
ECONOMIC PROBLEM						
HOSTILITY						
UNEMPLOYMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2012	8443101	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-16415879	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PULMONARY HYPERTENSION	ABILIFY	S			2 MTH	
WRONG TECHNIQUE IN DRUG USAGE PROCESS	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Mar-2012	8430530	NON-EXPEDITED	N	OT	US-PFIZER INC-2012049897		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MANIA	ZOLOFT	S		UNK		PFIZER
ANXIETY	CELEXA	S		UNK		
INSOMNIA	PAXIL	S		5 mg, UNK		
WEIGHT INCREASED	PROZAC	S		UNK		
	ATIVAN	S		0.5 mg, 3x/day		
	LEXAPRO	S		UNK		
	BROVANA	C		15 ug, 2x/day		
	BUDESONIDE	C		0.25 mg, 2x/day		
	IPRATROPIUM BROMIDE	C		0.2 %, 1x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Mar-2012	8447002	EXPEDITED (15-DAY)	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-16422461		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
THROMBOSIS	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Mar-2012	8461083	EXPEDITED (15-DAY)	N	OT	DSA_55286_2012	20 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	WELLBUTRIN XL	S		(300 MG,)		
	VIIBRYD	S		(DF)		
	LEXAPRO	S		(DF)		
	AMBIEN	S		(DF)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Mar-2012	8453640	NON-EXPEDITED	N		US-PFIZER INC-2012060644		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANXIETY	EFFEXOR XR	S	ORAL	150 mg, 1x/day (1 cap po nightly)		PFIZER
BLOOD PRESSURE DECREASED	EFFEXOR XR	S	ORAL	75 mg, 1x/day (1 cap po nightly)		PFIZER
DEPRESSION	LEXAPRO	S		UNK		
FEELING ABNORMAL	LEXAPRO	S		60 mg, daily		
OBSESSIVE THOUGHTS	METOPROLOL SUCCINATE	S		50 mg, daily		
WEIGHT INCREASED	ELAVIL	C		UNK		
APATHY	NICODERM CQ	C		UNK		
HUNGER	DEXIDRINE	C		UNK		
NICOTINE DEPENDENCE	OXYBUTYNIN	C		5 mg		
ONYCHOPHAGIA	ATIVAN	C		0.5 mg 1 1/2/day		
ANGER	MICRONOR	C		UNK		
CRYING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Mar-2012	8454623	EXPEDITED (15-DAY)	N	CA	US-FRI-1000028952	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COARCTATION OF THE AORTA	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Mar-2012	8454923	EXPEDITED (15-DAY)	Y	DE	NL-ASTRAZENECA-2012SE 15410	26 YR	Female	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COMPLETED SUICIDE	SEROQUEL	S	ORAL			ZENECA
DEATH	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2012	6962634	EXPEDITED (15-DAY)	Y	HO	US-PFIZER INC-2009187922	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSARTHRIA	DESVENLAFAXINE	S	ORAL	Blinded therapy daily	75 DAY	PFIZER
MENTAL STATUS CHANGES	UNSPECIFIED INGREDIENT	S	ORAL	Blinded therapy daily	75 DAY	PFIZER
HYPERTENSION	UNSPECIFIED INGREDIENT	S	ORAL	Blinded therapy daily	75 DAY	PFIZER
CONDITION AGGRAVATED	DESVENLAFAXINE	S	ORAL	Blinded therapy daily	26 DAY	PFIZER
HYPOKALAEMIA	UNSPECIFIED INGREDIENT	S	ORAL	Blinded therapy daily	26 DAY	PFIZER
POLYMEDICATION	UNSPECIFIED INGREDIENT	S	ORAL	Blinded therapy daily	26 DAY	PFIZER
	LYRICA	S	ORAL	75 mg, 1x/day		PFIZER
	IBUPROFEN	S	ORAL	800 mg, 3x/day		PFIZER
	LORATADINE	S	ORAL	10 mg, 1x/day		PFIZER
	ROBAXIN	S	ORAL	750 mg, 3x/day		PFIZER
	ROBAXIN	S		UNKNOWN		PFIZER
	CLONAZEPAM	S	ORAL	1 mg, 2x/day		
	LEXAPRO	S	ORAL	20 mg, 1x/day		
	LEXAPRO	S				
	ABILIFY	S	ORAL	15 mg, 2x/day		
	FLUTICASONE	S		2 sprays daily Route: IN		
	VICODIN	S	ORAL	5/500 PRN		
	ZESTORETIC	S	ORAL	20/12.5 daily		
	AMBIEN	S	ORAL	10 mg, 1x/day		
	VIVELLE	S	TRANSDERMAL	0.1 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2012	8456001	EXPEDITED (15-DAY)	N	CA	US-FRI-1000028955	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CRANIOSYNOSTOSIS	LEXAPRO	S	TRANSPLACENTAL			
CONGENITAL ANOMALY						
FOETAL EXPOSURE DURING PREGNANCY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2012	8456256	EXPEDITED (15-DAY)	N	CA	US-FRI-1000028957	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CLEFT LIP	LEXAPRO	S	TRANSPLACENTAL			
CLEFT PALATE						
CONGENITAL ANOMALY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Mar-2012	8434788	EXPEDITED (15-DAY)	N	HO,CA,OT	US-FRI-1000028169		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL	10 mg		
COARCTATION OF THE AORTA	LEXAPRO	S			7 MTH	
ATRIOVENTRICULAR BLOCK COMPLETE						
AUTISM						
DEVICE MALFUNCTION						
HYPOVOLAEMIA						
INGUINAL HERNIA						
PREMATURE BABY						
PULMONARY ARTERY STENOSIS						
RESPIRATORY DISTRESS						
RIGHT VENTRICULAR HYPERTROPHY						
UMBILICAL CORD ABNORMALITY						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Mar-2012	8457792	EXPEDITED (15-DAY)	N	HO,OT	US-US-EMD SERONO, INC.-7117365	49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SELF-INJURIOUS IDEATION	REBIF	S	SUBCUTANEOUS			
DEPRESSION	LEXAPRO	S				
FATIGUE	CANNABIS SATIVA SUBSP. INDICA TOP	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Mar-2012	8487846	NON-EXPEDITED	N		PHHY2011US62097		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INSOMNIA	FANAPT	S		8 MG, BID		
ABNORMAL BEHAVIOUR	SAPHRIS	S				
WEIGHT INCREASED	LEXAPRO	S				
	SEROQUEL	S				
	RISPERDAL	S				
	PRISTIQ EXTENDED RELEASE	C				
	EFFEXOR XR	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Mar-2012	6956961	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20090307044	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSARTHRIA	IBUPROFEN	S	ORAL			
MENTAL STATUS CHANGES	DESVENLAFAXINE SUCCINATE	S	ORAL			
HYPERTENSION	DESVENLAFAXINE SUCCINATE	S	ORAL			
HYPOKALAEMIA	PLACEBO	S	ORAL			
POLYMEDICATION	PLACEBO	S	ORAL			
ASTHENIA	LEXAPRO	S	ORAL			
HEADACHE	LEXAPRO	S	ORAL			
	CLONAZEPAM	S	ORAL			
	ABILIFY	S	ORAL			
	FLUTICASONE	S	INHALATION			
	LORATADINE	S	ORAL			
	VICODIN	S	ORAL	5/500 as needed		
	ZESTORETIC	S	ORAL	20/12.5 daily		
	AMBIEN	S	ORAL			
	VIVELLE	S	TRANSDERMAL			
	ROBAXIN	S				
	LYRICA	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Mar-2012	8461833	EXPEDITED (15-DAY)	N	CA	US-FRI-1000028973		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CRANIOSYNOSTOSIS	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Mar-2012	8438314	EXPEDITED (15-DAY)	Y		JP-FRI-1000028736	83 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	LEXAPRO	S	ORAL	10 mg		
VOMITING	EPERISONE HYDROCHLORIDE	C	ORAL	100 mg		
HEADACHE	NEXIUM	C	ORAL	20 mg		
FEELING ABNORMAL	TEPRENONE	C	ORAL	180 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Mar-2012	8430015	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-16409419	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEAFNESS UNILATERAL	ABILIFY	S	ORAL			
	LIPITOR	S				
	LEXAPRO	S				
	XANAX	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Mar-2012	8468469	EXPEDITED (15-DAY)	N	HO	US-FRI-1000024018	90 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GASTROINTESTINAL HAEMORRHAGE	LEXAPRO	S	ORAL	5 mg		
DIVERTICULITIS	LEXAPRO	S	ORAL	10 mg		
FATIGUE	PROSCAR	C				
POOR QUALITY SLEEP	FERROUS SULFATE	C				
AMNESIA	NEXIUM	C				
	DOCUSATE SODIUM	C				
	MULTI-VITAMIN	C				
	LISINOPRIL	C	ORAL	5 mg		
	SIMVASTATIN	C	ORAL	10 mg		
	NORVASC	C	ORAL	2.5 mg		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Mar-2012	8471264	NON-EXPEDITED	N		US-PFIZER INC-2012069691	82 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRURITUS	ALDACTONE	S		UNK		PFIZER
	FUROSEMIDE	S		UNK		
	ATIVAN	S		UNK		
	VITAMIN C	S		UNK		
	LEXAPRO	S		10 mg, 2x/day		
	LEXAPRO	S		10 mg, 1x/day		
	PRILOSEC	S		UNK		
	FISH OIL	S		UNK		
	TOPROL XL	C		UNK		
	GABAPENTIN	C		UNK		
	CARAFATE	C		UNK		
	ATARAX	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Mar-2012	8473900	DIRECT	N	OT		42 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AGGRESSION	LEXAPRO	S	ORAL	10mg		
PHYSICAL ASSAULT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Mar-2012	8476432	DIRECT					Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MEDICATION ERROR	LEXAPRO	S	ORAL	TABLET BY MOUTH		
DRUG DISPENSING ERROR	LIPITOR	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Mar-2012	8504152	NON-EXPEDITED	Y	OT	PHEH2009US13124	71 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	GLEEVEC	S	ORAL	400 MG, QD, ORAL		
CRYING	LEXAPRO	S				
INSOMNIA	CYMBALTA	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Mar-2012	8485694	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000029298		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE SPASTICITY	LEXAPRO	S				
MUSCULOSKELETAL STIFFNESS	WELLBUTRIN	S				
PAIN	CYMBALTA	S				
	TRAMADOL HYDROCHLORIDE	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Mar-2012	8497597	DIRECT		DS,OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TINNITUS	LOSARTAN POTASSIUM	S		100MG/ CUT TO 50MG & ALSO TO 75MG 1 PER DAY		
MACULAR DEGENERATION	LEXAPRO	S		5MG 1 X PER NITE		
ARTHRITIS						
EYE DISORDER						
GLUCOSE TOLERANCE IMPAIRED						
SPINAL COLUMN STENOSIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Mar-2012	8555336	NON-EXPEDITED	Y	OT	PHHY2011US55324		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION, VISUAL	EXELON	S	TRANSDERMAL	1 DF, ONE PER DAY (4.6 MG), TRANSDERMAL		
	LEXAPRO	S		5 MG, PER DAY		
	NAMENDA	S		2 DF, 5 MG PER DAY		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Apr-2012	8488078	EXPEDITED (15-DAY)	Y	OT	BR-FRI-1000029484	34 YR	Female	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VAGINAL HAEMORRHAGE	LEXAPRO	S	ORAL	20 mg		
BLOOD PRESSURE INCREASED	LEXAPRO	S	ORAL	10 mg		
PAIN IN EXTREMITY	ALPRAZOLAM	C	ORAL	1 mg		
DYSPEPSIA	ALPRAZOLAM	C				
HYPERHIDROSIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2012	8490835	EXPEDITED (15-DAY)	Y	OT	2012SP000518	28 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABORTION SPONTANEOUS	LATUDA	S	ORAL			
	METFORMIN HYDROCHLORIDE	S				
	LEXAPRO	S				
	UNSPECIFIED INGREDIENT	S				
	ASPIRIN	S				
	LOVENOX	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2012	8491766	EXPEDITED (15-DAY)	Y	LT	AU-FRI-1000029495	23 YR	Male	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL			
ERECTILE DYSFUNCTION						
LOSS OF LIBIDO						
MEMORY IMPAIRMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2012	8492086	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20120400391		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCULOSKELETAL STIFFNESS	TRAMADOL HYDROCHLORIDE	S	UNKNOWN			
MUSCLE SPASTICITY	UNSPECIFIED INGREDIENT	S	UNKNOWN			
PAIN	CYMBALTA	S	UNKNOWN			
DRUG INEFFECTIVE	LEXAPRO	S	UNKNOWN			
	WELLBUTRIN	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2012	8492306	EXPEDITED (15-DAY)	N	OT	US-GLAXOSMITHKLINE-A0972041A	48 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	WELLBUTRIN	S	ORAL			GLAXOSMITHKLINE
PARANOIA	SEROQUEL	S	UNKNOWN	300MGD per day	3 YR	GLAXOSMITHKLINE
MOOD SWINGS	LEXAPRO	S	UNKNOWN			
INSOMNIA	PRISTIQ EXTENDED RELEASE	S	UNKNOWN	50MGD per day		
DRUG INEFFECTIVE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Apr-2012	8411275	EXPEDITED (15-DAY)	Y	HO	JP-JNJFOC-20120205844	59 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEPATIC FUNCTION ABNORMAL	RISPERDAL	S	ORAL	0.5-2 mg/day		
	RISPERDAL	S	ORAL	0.5-2 mg/day		
	ZOLOFT	S	ORAL			
	ZOLOFT	S	ORAL	25-100/day		
	ZOLOFT	S	ORAL	25-100/day		
	ZOLOFT	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL	10-20/day		
	MAGNESIUM OXIDE	C	ORAL	100-600/day		
	SENNOSIDE	C	ORAL			
	SULPIRIDE	C	ORAL			
	BROTIZOLAM	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Apr-2012	8484636	EXPEDITED (15-DAY)	Y	HO	US-FRI-1000028430	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BACTERAEMIA	LEXAPRO	S		40 mg		
DISORIENTATION	ZYVOX	S				
OVERDOSE						
SEROTONIN SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Apr-2012	8493745	EXPEDITED (15-DAY)	Y	OT	IE-FRI-1000029534		Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VAGINAL HAEMORRHAGE	LEXAPRO	S	ORAL			
CONTUSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Apr-2012	8494069	EXPEDITED (15-DAY)	N	CA	US-FRI-1000029479	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			
ATRIAL SEPTAL DEFECT						
CONGENITAL ANOMALY						
RESPIRATORY DISTRESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Apr-2012	8510434	DIRECT	Y			60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	ESCITALOPRAM OXALATE	S	ORAL	20MG ONE QD ORAL		MYLAN
ANXIETY	LEXAPRO	S				
DISEASE RECURRENCE						
DRUG INEFFECTIVE						
PRODUCT SUBSTITUTION ISSUE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Apr-2012	8432307	EXPEDITED (15-DAY)	N	HO,CA,OT	US-FRI-1000028126	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			
ATRIAL SEPTAL DEFECT						
CARDIOMEGALY						
HYDRONEPHROSIS						
HYPERTENSION						
JAUNDICE NEONATAL						
NODAL RHYTHM						
URINARY TRACT INFECTION NEONATAL						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Apr-2012	8432837	EXPEDITED (15-DAY)	N	HO,CA	US-FRI-1000028145		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONGENITAL TRICUSPID VALVE ATRESIA	LEXAPRO	S	TRANSPLACENTAL			
TRANSPOSITION OF THE GREAT VESSELS	PRENATABS FA	C				
VENTRICULAR SEPTAL DEFECT	IRON	C				
PULMONARY VALVE STENOSIS	PEPCID	C				
URINARY TRACT INFECTION	COLACE	C				
PLEURAL EFFUSION						
PNEUMOTHORAX						
SUBDURAL HAEMORRHAGE						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Apr-2012	8466572	EXPEDITED (15-DAY)		HO	AU-PFIZER INC-2012063736	40 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Migraine	BLINDED PLACEBO	S	ORAL	UNK mg, 1x/day		PFIZER
	BLINDED PLACEBO	S	ORAL	UNK mg, 1x/day		PFIZER
	BLINDED VARENICLINE TARTRATE	S	ORAL	UNK mg, 1x/day		PFIZER
	BLINDED VARENICLINE TARTRATE	S	ORAL	UNK mg, 1x/day		PFIZER
	BLINDED PLACEBO	S	ORAL	UNK mg, 2x/day		PFIZER
	BLINDED PLACEBO	S	ORAL	UNK mg, 2x/day		PFIZER
	BLINDED VARENICLINE TARTRATE	S	ORAL	UNK mg, 2x/day		PFIZER
	BLINDED VARENICLINE TARTRATE	S	ORAL	UNK mg, 2x/day		PFIZER
	BLINDED PLACEBO	S	ORAL	UNK mg, 2x/day		PFIZER
	BLINDED PLACEBO	S	ORAL	UNK mg, 2x/day		PFIZER
	BLINDED VARENICLINE TARTRATE	S	ORAL	UNK mg, 2x/day		PFIZER
	BLINDED VARENICLINE TARTRATE	S	ORAL	UNK mg, 2x/day		PFIZER
	Depo-Provera	S	INTRAMUSCULAR	UNK, every 3 months		PFIZER
	LEXAPRO	S	ORAL	20 mg, daily		
	CYMBALTA	S	ORAL	30 mg, daily		
	THYROXINE	C	ORAL	50 mg, daily		
	ESOMEPRAZOLE	C	ORAL	20 mg, as needed		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Apr-2012	8433984	EXPEDITED (15-DAY)	N	HO,CA,OT	US-FRI-1000028153		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINA BIFIDA	LEXAPRO	S	TRANSPLACENTAL			
ARNOLD-CHIARI MALFORMATION	PRENATE ELITE	C	TRANSPLACENTAL			
HYDROCEPHALUS	PEPCID	C	TRANSPLACENTAL			
DILATATION VENTRICULAR	PREVACID	C	TRANSPLACENTAL			
MICROCEPHALY	TUMS	C	TRANSPLACENTAL			
HYPOGLYCAEMIA	ROLAIDS	C	TRANSPLACENTAL			
HYPOTENSION	PRILOSEC	C	TRANSPLACENTAL			
DEHYDRATION	TYLENOL	C	TRANSPLACENTAL			
EPILEPSY						
HYDROCELE						
PHIMOSIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Apr-2012	8498321	EXPEDITED (15-DAY)	Y	HO	JP-FRI-1000028442	65 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	LEXAPRO	S	ORAL	20 mg		
	SULPIRIDE	C	ORAL			
	ANAFRANIL	C	ORAL			
	CYMBALTA	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Apr-2012	8498407	EXPEDITED (15-DAY)	N	OT	US-FRI-1000029453	18 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HOMICIDAL IDEATION	LEXAPRO	S	ORAL	10 MG		
FEELING ABNORMAL	LEXAPRO	S			14 DAY	
NAUSEA	KLONOPIN	C				
FATIGUE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Apr-2012	8485767	EXPEDITED (15-DAY)		HO	IE-FRI-1000029419	80 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONDITION AGGRAVATED	LEXAPRO	S				
BLOOD SODIUM DECREASED	UNSPECIFIED INGREDIENT	S				
APHAGIA						
CARDIAC FAILURE						
FALL						
FLUID INTAKE REDUCED						
GENERAL PHYSICAL HEALTH DETERIORATION						
NO THERAPEUTIC RESPONSE						
PLEURAL EFFUSION						
PSYCHOTIC DISORDER						
URINARY TRACT INFECTION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Apr-2012	8478941	EXPEDITED (15-DAY)	Y	HO	NL-FRI-1000029362	81 YR	Female	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANXIETY	CITALOPRAM	S	ORAL	20 mg		
FEELING OF DESPAIR	CITALOPRAM	S				
CONDITION AGGRAVATED	CITALOPRAM	S	ORAL	20 mg		
NAUSEA	CITALOPRAM	S	ORAL	10 mg		
TENSION	CITALOPRAM	S	ORAL	20 mg		
NERVOUSNESS	LEXAPRO	S	ORAL	10 mg		
MALAISE	LEXAPRO	S				
	ALPRAZOLAM	C	ORAL			
	OXAZEPAM	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Apr-2012	8498096	EXPEDITED (15-DAY)	Y	OT	US-GLAXOSMITHKLINE-A0972437A	42 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CEREBROVASCULAR ACCIDENT	WELLBUTRIN	S	ORAL			GLAXOSMITHKLINE
MUSCLE SPASTICITY	LEXAPRO	S	UNKNOWN			
MUSCULOSKELETAL STIFFNESS	CYMBALTA	S	ORAL			GLAXOSMITHKLINE
PAIN	TRAMADOL HYDROCHLORIDE	S	UNKNOWN			GLAXOSMITHKLINE
DRUG INEFFECTIVE	UNSPECIFIED INGREDIENT	S	UNKNOWN		4 YR	GLAXOSMITHKLINE
HYPERTENSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Apr-2012	8501352	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-16490807	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ORTHOSTATIC HYPOTENSION	ABILIFY	S		Initially given 5 mg then reduced to 2.5mg		
LOSS OF CONSCIOUSNESS	LEXAPRO	S		Dose:5mg		
	VITAMINS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Apr-2012	8502037	EXPEDITED (15-DAY)	N	OT	US-FRI-1000029593		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL			
HEART RATE INCREASED						
NEPHROLITHIASIS						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Apr-2012	8693880	NON-EXPEDITED	Y	OT	AUR-APL-2011-05649	38 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANGIOEDEMA	LISINOPRIL (LISINOPRIL)	S		UNKNOWN		
DRUG HYPERSENSITIVITY	PENICILLIN	S		UNKNOWN		
LIP SWELLING	BENADRYL	S				
SWOLLEN TONGUE	LEXAPRO	S				
	MOBIC	S	ORAL	1 D, ORAL		
	PRINZIDE	S	ORAL	1 D, ORAL		
	CELEBREX	C				
	ALLEGRA-D (ALLEGRA-D)	C				
	AMOXICILLIN	C				
	NASONEX	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Apr-2012	8476993	EXPEDITED (15-DAY)	Y	OT	BE-FRI-1000029299	44 YR	Female	BEL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EYE HAEMORRHAGE	LEXAPRO	S	ORAL	10 mg		
	LEXAPRO	S	ORAL	15 mg		
	LEXAPRO	S	ORAL	20 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Apr-2012	8525074	DIRECT	Y	OT		21 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANXIETY	ABILIFY	S	ORAL	5MG DAILY ORAL		
PANIC ATTACK	LEXAPRO	S	ORAL	10MG DAILY ORAL		FOREST
AKATHISIA	CITALOPRAM	S				
AMNESIA						
DISTURBANCE IN ATTENTION						
DYSKINESIA						
MEMORY IMPAIRMENT						
MENTAL STATUS CHANGES						
RESTLESSNESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Apr-2012	8468680	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000029135	38 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LOSS OF CONSCIOUSNESS	LEXAPRO	S	ORAL	10 mg		
HEADACHE	LITHIUM CARBONATE	C	ORAL	400 mg		
PHOTOPSIA	LUDIOMIL	C	ORAL	20 mg		
NAUSEA	MYSLEE	C	ORAL	10 mg		
	BROTIZOLAM	C	ORAL	0.25 mg		
	NIZATIDINE	C	ORAL	150 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Apr-2012	8505816	NON-EXPEDITED	Y		US-PFIZER INC-2012090048	66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
URINE ODOUR ABNORMAL	LIPITOR	S	ORAL	40 mg, daily		PFIZER
	LIPITOR	S	ORAL	40 mg, daily		PFIZER
	LEXAPRO	S		10 mg, daily		
	LEXAPRO	S		10 mg, daily		
	GLUCOPHAGE	C		1000 mg, 2x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Apr-2012	8507862	EXPEDITED (15-DAY)	N	CA	US-FRI-1000029638	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANAL ATRESIA	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Apr-2012	8445161	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000024586		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUPRAVENTRICULAR EXTRASYSTOLES	LEXAPRO	S	TRANSPLACENTAL	20 mg		
	LEXAPRO	S			8 MTH	
	VALTREX	C	TRANSPLACENTAL	500 mg		
	ZOFRAN	C	TRANSPLACENTAL	4 mg every 8 hours as needed		
	PRENATABS FA	C	TRANSPLACENTAL			
	ZINC SULFATE	C	TRANSPLACENTAL			
	FISH OIL	C	TRANSPLACENTAL			
	VITAMIN B12	C	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Apr-2012	8509553	NON-EXPEDITED			US-PFIZER INC-2012088013	55 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	MORPHINE SULFATE	S		UNK		PFIZER
	LEXAPRO	S		UNK		
	SULFUR	S		UNK		
	OXYCODONE	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Apr-2012	8510731	EXPEDITED (15-DAY)	N	OT	US-FRI-1000029674	20 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Stress fracture	LEXAPRO	S	ORAL	10 mg		
OFF LABEL USE	MULTIVITAMINS	C				
	CALCIUM CARBONATE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Apr-2012	8511027	NON-EXPEDITED	Y		US-PFIZER INC-2012089981		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RENAL PAIN	LIPITOR	S	ORAL	40 mg, daily		PFIZER
URINE ODOUR ABNORMAL	LIPITOR	S				PFIZER
MUSCULAR WEAKNESS	LEXAPRO	S		10 mg, daily		
	GLUCOPHAGE	C		1000 mg, 2x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Apr-2012	8523360	EXPEDITED (15-DAY)	N	OT	DSA_56063_2012		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MUSCLE SPASTICITY	WELLBUTRIN	S	ORAL	(DF ORAL)		
MUSCULOSKELETAL STIFFNESS	TRAMADOL HYDROCHLORIDE	S		(DF)		
DRUG INEFFECTIVE	LEXAPRO	S		(DF)		
PAIN	CYMBALTA	S	ORAL	(DF ORAL)		
CEREBROVASCULAR ACCIDENT	UNSPECIFIED INGREDIENT	S		(DF)		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Apr-2012	8530320	DIRECT	Y	HO		65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	LEXAPRO	S				
INSOMNIA	PREMARIN	C				
DIZZINESS						
FALL						
PNEUMOCEPHALUS						
SKULL FRACTURE						
SYNCOPE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Apr-2012	8362554	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2012022337	69 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
AMNESIA	GEODON	S		40 mg, Daily		PFIZER
MENTAL DISORDER	GEODON	S		80 mg, Daily		PFIZER
INSOMNIA	RISPERDAL	S		4 mg, Daily		
CEREBROVASCULAR ACCIDENT	RISPERDAL	S		3 mg, Daily		
NERVOUS SYSTEM DISORDER	RISPERDAL	S		2 mg, Daily		
STRESS	RISPERDAL	S		UNK		
MALAISE	LEXAPRO	S		20 mg, Daily		
	KLONOPIN	C		1 mg, 3x/day		
	KLONOPIN	C				
	WELLBUTRIN	C		75 mg, 2x/day		
	ZOCOR	C		40 mg, daily		
	COREG	C		6.25 mg, daily		
	ALTACE	C		5 mg, daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Apr-2012	8494557	EXPEDITED (15-DAY)	Y	OT	IE-FRI-1000029585		Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LIVER FUNCTION TEST ABNORMAL	LEXAPRO	S	ORAL	5 mg		
	LEXAPRO	S	ORAL	10 mg		
	NEXIUM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Apr-2012	8515903	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000029790		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Apr-2012	8516762	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000029699	17 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABORTION SPONTANEOUS	LEXAPRO	S	ORAL			
MATERNAL EXPOSURE DURING PREGNANCY	LATUDA	S	ORAL			
	METFORMIN HYDROCHLORIDE	S				
	ASPIRIN	S				
	LOVENOX	S				
	FOLIC ACID	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Apr-2012	8516913	EXPEDITED (15-DAY)	Y	OT	JP-GLAXOSMITHKLINE-B0783764A	37 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ERYTHEMA MULTIFORME	LAMICTAL	S	ORAL	25MG Alternate days	2 WEEK	GLAXOSMITHKLINE
TOXIC SKIN ERUPTION	PAXIL	S	ORAL	20MG Per day		GLAXOSMITHKLINE
DRUG ERUPTION	DEPAKENE	S	ORAL	600MG Per day	15 DAY	
PYREXIA	LEXAPRO	S	ORAL	10MG Per day	8 WEEK	
CHILLS	CLOTIAZEPAM	S	ORAL	15MG Per day		
MYALGIA	MOSAPRIDE CITRATE	S	ORAL	10MG Per day		GLAXOSMITHKLINE
ERYTHEMA						
GENERALISED ERYTHEMA						
MALAISE						
RASH						
RASH GENERALISED						
SWELLING FACE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Apr-2012	8517689	EXPEDITED (15-DAY)	Y	LT	JP-FRI-1000029813		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONSTIPATION	LEXAPRO	S	ORAL	10 mg		
SEPSIS	LEXAPRO	S	ORAL	20 mg		
	CYMBALTA	C	ORAL	50 mg		
	AMITRIPTYLINE HYDROCHLORIDE	C	ORAL	40 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2012	8521189	EXPEDITED (15-DAY)	Y	OT	US-MYLANLABS-2012S1007501	29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MATERNAL EXPOSURE DURING PREGNANCY	METFORMIN HYDROCHLORIDE	S				MYLAN
ABORTION SPONTANEOUS	LATUDA	S	ORAL			
	LEXAPRO	S				
	ASPIRIN	S				
	LOVENOX	S				
	PYRIDOXINE HYDROCHLORIDE	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Apr-2012	8524354	EXPEDITED (15-DAY)	N	HO	US-PURDUE-USA-2012-0085521	92 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ASTHENIA	DOCUSATE SODIUM	S				PURDUE PHARMA
SOMNOLENCE	TENORMIN	S				
CONFUSIONAL STATE	BENICAR	S				
BLOOD SODIUM DECREASED	LEXAPRO	S				
	NAMENDA	S				
	XANAX	S				
	TRAVATAN	S				
	SYNTHROID	S				
	ASCORBIC ACID\CALCIUM PANTOTHENATE \ERGOCALCIFEROL\PYRIDOXINE HYDROCHLORIDE\RETINOL \RIBOFLAVIN\THIAMINE HYDROCHLORIDE	S				
	ASCORBIC ACID	S				
	CALCIUM CARBONATE	S				
	ASPIRIN	S				
	LUTEIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Apr-2012	8524404	EXPEDITED (15-DAY)	N	OT	US-FRI-1000029729	36 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OLIGOHYDRAMNIOS	LEXAPRO	S	ORAL	40 mg		
CONVULSION	LASIX	C				
MATERNAL EXPOSURE DURING PREGNANCY	POTASSIUM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Apr-2012	8524507	EXPEDITED (15-DAY)	N	CA,OT	US-FRI-1000029730	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC MURMUR	LEXAPRO	S	TRANSPLACENTAL	40 mg		
CONGENITAL CARDIOVASCULAR ANOMALY	LASIX	C				
UNEVALUABLE EVENT	POTASSIUM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Apr-2012	8525561	EXPEDITED (15-DAY)	Y	OT	US-SANOFI-AVENTIS-2012SA024842	28 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABORTION SPONTANEOUS	LOVENOX	S				
MATERNAL EXPOSURE DURING PREGNANCY	UNSPECIFIED INGREDIENT	S	ORAL			
	METFORMIN HYDROCHLORIDE	S				
	ASPIRIN	S				
	UNSPECIFIED INGREDIENT	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Apr-2012	8527641	DIRECT	Y	HO		87 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MENTAL STATUS CHANGES	LEXAPRO	S				
CONFUSIONAL STATE						
DISORIENTATION						
FALL						
UNRESPONSIVE TO STIMULI						

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Apr-2012	8529552	DIRECT	N	DE,HO,DS,LT,CA,OT,RI		21 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GUN SHOT WOUND	LEXAPRO	S	ORAL	daily		
COMPLETED SUICIDE						
PARANOIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Apr-2012	8538082	DIRECT	N	OT		50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PAIN IN EXTREMITY	LEXAPRO	S	ORAL	5 MG 1 X DAY ORAL		MYLAN
OEDEMA PERIPHERAL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Apr-2012	8422872	EXPEDITED (15-DAY)	N	OT	US-GLAXOSMITHKLINE-A0967017A	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EPILEPSY	LAMICTAL	S	ORAL	150MG Twice per day		GLAXOSMITHKLINE
SOMNOLENCE	PROVERA	S	ORAL	10MG Per day	20 YR	
TREMOR	PREMARIN	S	ORAL	.625MG Per day		
Balance disorder	TOPAMAX	S	ORAL	300MG per day		GLAXOSMITHKLINE
DRUG INTERACTION	VIMPAT	S	UNKNOWN	100MG Four times per day		GLAXOSMITHKLINE
DRUG INEFFECTIVE	LEXAPRO	S	UNKNOWN	20MG Per day		

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Apr-2012	8531661	NON-EXPEDITED	N	OT	US-TEVA-US022005	88 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HALLUCINATION	PROVIGIL	S	ORAL	100 Milligram;		
ORAL CANDIDIASIS	RISPERDAL	S	ORAL	1.25 Milligram;		
ANXIETY	RISPERDAL	S	ORAL	.25 Milligram;		
	LEXAPRO	S	ORAL	20 Milligram;		
	NAMENDA	C	ORAL	20 Milligram;		
	PROTONIX	C	ORAL	20 Milligram;		
	POTASSIUM	C	ORAL			
	LASIX	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Apr-2012	8531851	NON-EXPEDITED	N		US-PFIZER INC-2012101146	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LIBIDO DECREASED	CARDURA	S		UNK		PFIZER
	LEXAPRO	S	ORAL	10 mg, 1x/day (10mg, 1 in 1 D)		
	LEXAPRO	S		10 mg, daily		
	TAMSULOSIN HYDROCHLORIDE	S		UNK		
	WELLBUTRIN	C		UNK		
	TRICOR	C		UNK		
	LIPITOR	C		UNK		
	ALPHAGAN P	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Apr-2012	8532232	NON-EXPEDITED	Y	HO	US-TEVA-US025061	14 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INTENTIONAL OVERDOSE	PROVIGIL	S	ORAL			
SUICIDE ATTEMPT	LEXAPRO	S				
DELIRIUM	DEPAKOTE	C				
HYPERVIGILANCE	AMITRIPTYLINE	C				
ANXIETY						
CLONUS						
DIARRHOEA						
DRY MOUTH						
HYPERHIDROSIS						
TACHYCARDIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-May-2012	8283678	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2011292301	26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RESPIRATORY TRACT INFECTION	ZOLOFT	S		25mg, a day for seven days	7 DAY	PFIZER
BIPOLAR II DISORDER	ZOLOFT	S		50mg, for four weeks		PFIZER
DEPRESSION	ZOLOFT	S		75 mg, 1x/day		PFIZER
SINUSITIS	ZOLOFT	S		20 mg, 1x/day for 4 weeks		PFIZER
OBESITY	ZOLOFT	S		50 mg, 1x/day		PFIZER
MIGRAINE	ZOLOFT	S		100 mg, 1x/day		PFIZER
WITHDRAWAL SYNDROME	ZOLOFT	S		50 mg, 2x/day		PFIZER
DRUG INEFFECTIVE	ZOLOFT	S		75 mg, UNK		PFIZER
AFFECTIVE DISORDER	ZOLOFT	S	ORAL	50 mg, UNK		PFIZER
HYSTERECTOMY	ZOLOFT	S		100 mg, for 6 months		PFIZER
SALPINGO-OOPHORECTOMY BILATERAL	XANAX	S		0.25 mg, 2x/day		PFIZER
CHOLELITHIASIS	XANAX	S		0.5 mg, every 8 hours		PFIZER

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ARTERIOSCLEROSIS	EFFEXOR	S		37.5 mg, 1x/day	7 DAY	PFIZER
MEMORY IMPAIRMENT	EFFEXOR	S		75 mg, 1x/day		PFIZER
FOLLICULITIS	CALAN	S		UNK		PFIZER
STRESS	INDERAL LA	S		60mg 1 at night		PFIZER
ANXIETY	ULTRAM	S		50 mg, as needed, every 8 hours		
SEBORRHOEA	ELAVIL	S		UNK		
LIBIDO DECREASED	LEXAPRO	S		10 mg, UNK		
FEELING ABNORMAL	WELLBUTRIN	S		200mg, one daily	3 DAY	
AGITATION	WELLBUTRIN	S		150 mg, 1x/day		
INSOMNIA	WELLBUTRIN	S		300 mg, UNK		
	TOPAMAX	S		25, twice a day for seven days		
	TOPAMAX	S		50 mg and 25 mg in the morning for 7 days		
	TOPAMAX	S		25 mg, x7days in the morning		
	TOPAMAX	S		25 mg, at night for 17 days		
	LORTAB	S		7.5/500 one every 6-8 hours as needed		
	LORTAB	S		5/500 one every 8 hours as needed	16 DAY	
	LUNESTA	S		UNK		
	MIRAPEX	S				
	CYMBALTA	S		30 mg, 1x/day		
	PAXIL	S	ORAL	10 mg, 1x/day		
	PAXIL	S		20 mg, 1x/day		
	MIDRIN	S		two capsules at start of migraine		
	MOTRIN	S				
	EXCEDRIN MIGRAINE	S				
	ORTHO-NOVUM	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-May-2012	8474807	NON-EXPEDITED	N		US-PFIZER INC-2012072681	29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WITHDRAWAL SYNDROME	PRISTIQ EXTENDED RELEASE	S	ORAL	15 mg, daily		PFIZER
FEELING ABNORMAL	PRISTIQ EXTENDED RELEASE	S				PFIZER
HEADACHE	LEXAPRO	S		10 mg, daily		
DIZZINESS	LEXAPRO	S				
NAUSEA	ZYRTEC	C		10 mg, daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-May-2012	8506346	EXPEDITED (15-DAY)	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-16504102	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PERICARDIAL EFFUSION	ABILIFY	S	ORAL	QAM	3 MTH	
OEDEMA DUE TO CARDIAC DISEASE	CELEXA	S	ORAL	QAM		
ELECTROCARDIOGRAM QT PROLONGED	LEXAPRO	S				
WEIGHT INCREASED	EFFEXOR	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-May-2012	8510315	EXPEDITED (15-DAY)	N	OT	US-FRI-1000029664	46 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
LEGAL PROBLEM	LEXAPRO	S		10 mg		
MYOCARDIAL INFARCTION	TRAZODONE HYDROCHLORIDE	S		200 mg QHS		
BLOOD PRESSURE DECREASED	KLONOPIN	C				
HEART RATE DECREASED	NEURONTIN	C				
MALAISE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-May-2012	8520162	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000024535	22 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OESOPHAGEAL ACHALASIA	LEXAPRO	S		10 mg		
	LEXAPRO	S				
	LEXAPRO	S				
	ALPRAZOLAM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-May-2012	8554654	DIRECT	Y	OT		60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRODUCT SUBSTITUTION ISSUE	LEXAPRO	S	ORAL	20MG ONE QHS P.O.		TEVA
DEPRESSION	SYNTHROID	C				
SUICIDAL IDEATION	WELLBUTRIN XL	C				
	ZYPREXA	C				
	GLUCOPHAGE	C				
	VESICARE	C				
	LITHOBID 450 MG	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-May-2012	8544841	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030084	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TALIPES	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-May-2012	8545520	EXPEDITED (15-DAY)	N	OT	US-WATSON-2012-06804	46 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MYOCARDIAL INFARCTION	TRAZODONE HYDROCHLORIDE	S	ORAL	200 mg QHS		WATSON
LEGAL PROBLEM	LEXAPRO	S	ORAL	1 tab daily		
BLOOD PRESSURE DECREASED						
HEART RATE DECREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-May-2012	8545662	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030101	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MICROCEPHALY	LEXAPRO	S	TRANSPLACENTAL			
CONGENITAL ANOMALY						
CONGENITAL SPINAL CORD ANOMALY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-May-2012	8545680	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030171	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			
ATRIAL SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-May-2012	8535138	EXPEDITED (15-DAY)	Y	HO	CN-FRI-1000030072	38 YR	Male	CHN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GASTRIC ULCER	LEXAPRO	S	ORAL	10 mg		
	MIRTAZAPINE	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-May-2012	8545996	EXPEDITED (15-DAY)	N	OT	US-SHIRE-ALL1-2012-02058	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	VYVANSE	S	ORAL	50 mg, 3-4 times per week as req'd		SHIRE
CHILLS	VYVANSE	S	ORAL	30 mg, 1x/day:qd		SHIRE
YAWNING	AMOXAPINE	S	ORAL	UNK, 1x/day:qd		
PYREXIA	WELLBUTRIN	S	ORAL	UNK, 1x/day:qd		
TREMOR	LEXAPRO	S		UNK, 1x/day:qd		
DISTURBANCE IN ATTENTION						
DRUG INEFFECTIVE						
DRUG PRESCRIBING ERROR						
PRODUCT QUALITY ISSUE						
SLUGGISHNESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-May-2012	8546029	NON-EXPEDITED	Y		US-PFIZER INC-2012107268		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG HYPERSENSITIVITY	ZOLOFT	S		UNK		PFIZER
	DOXYCYCLINE HYCLATE	S		UNK		PFIZER
	TRAMADOL HYDROCHLORIDE	S		UNK		
	LEXAPRO	S		UNK		
	DURAGESIC	S		UNK		
	PAXIL	S		UNK		
	COMPAZINE	S		UNK		
	DROPERIDOL	S		UNK		
	CODEINE	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-May-2012	8547451	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030194	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CRANIOSYNOSTOSIS	LEXAPRO	S	TRANSPLACENTAL			
CONGENITAL ANOMALY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-May-2012	8547487	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-12P-163-0929570-00	38 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRURITUS	HUMIRA	S				
CHOKING SENSATION	LEXAPRO	S		Daily dose: 5mg		
SWELLING FACE	XANAX	S				
ABDOMINAL PAIN UPPER						
ANXIETY						
ARTHRALGIA						
BURNING SENSATION						
DIZZINESS						
DRUG INEFFECTIVE						
DYSPNOEA						
EYE SWELLING						
HEADACHE						
NAUSEA						
NECK PAIN						
PANIC ATTACK						
PHARYNGEAL OEDEMA						
PSORIASIS						
SWOLLEN TONGUE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-May-2012	8547757	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030207	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINA BIFIDA	LEXAPRO	S	TRANSPLACENTAL			
CONGENITAL HYDROCEPHALUS						
MULTIPLE CONGENITAL ABNORMALITIES						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-May-2012	8541718	EXPEDITED (15-DAY)	N	OT	PHHY2012US034939		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABORTION SPONTANEOUS	BUFFERIN	S				NOVARTIS
SUICIDAL IDEATION	MORPHINE	S				
PANIC ATTACK	CODEINE	S				
BLOOD PRESSURE INCREASED	MAXALT	S				
WEIGHT INCREASED	TOPAMAX	S				
CRYING	EFFEXOR	S				
BLOOD CHOLESTEROL INCREASED	INDERAL	S				
MICTURITION URGENCY	PROZAC	S				
BLOOD GLUCOSE INCREASED	PAXIL	S				
GASTRIC DISORDER	SERZONE	S				
INCORRECT DRUG ADMINISTRATION DURATION	LEXAPRO	S				
INCORRECT DOSE ADMINISTERED	ZANTAC	S				
MIGRAINE	LORTAB	S				
VOMITING	TYLENOL	S				
MATERNAL EXPOSURE DURING PREGNANCY	ADVIL	S				
DRUG INEFFECTIVE	ALEVE	S				
	BAYER ASPIRIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-May-2012	8548627	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2012-BP-09983BP	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SEXUAL DYSFUNCTION	FLOMAX	S	ORAL			BOEHRINGER INGELHEIM
	LEXAPRO	S	ORAL	10 mg		
	LEXAPRO	S				
	CARDURA	S				
	WELLBUTRIN	C				
	TRICOR	C				
	LIPITOR	C				
	ALPHAGAN P	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-May-2012	8558857	DIRECT	N	OT		53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME	LEXAPRO	S	ORAL	20MG 1/DAY ORAL		FOREST
INFLUENZA LIKE ILLNESS						
PARAESTHESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-May-2012	8192244	EXPEDITED (15-DAY)	Y	HO,DS,OT	2010SP063654	36 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREATMENT NONCOMPLIANCE	NUVARING	S				
DYSURIA	LEXAPRO	S				
MICTURITION URGENCY	REGLAN	S				
PULMONARY EMBOLISM	COUMADIN	S				
ABDOMINAL DISTENSION						
ACCIDENT AT WORK						
ACUTE SINUSITIS						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ADNEXA UTERI MASS						
ANGER						
APATHY						
ARTHRALGIA						
ARTHRITIS						
ASTHENIA						
BACK PAIN						
BIPOLAR DISORDER						
BLOOD 1,25-DIHYDROXYCHOLECALCIFEROL DECREASED						
BLOOD HOMOCYSTEINE INCREASED						
BRADYKINESIA						
BRUXISM						
CENTRAL NERVOUS SYSTEM LESION						
CEREBELLAR HAEMORRHAGE						
CHEST DISCOMFORT						
CONSTIPATION						
DIPLOPIA						
DIZZINESS						
DRUG INEFFECTIVE						
DRUG INTOLERANCE						
Dry eye						
DYSGEUSIA						
DYSMENORRHOEA						
DYSPNOEA						
EPSTEIN-BARR VIRUS INFECTION						
EYE INJURY						
EYE PAIN						
FATIGUE						
FEELING JITTERY						
FIBROMYALGIA						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FLATULENCE						
FOLATE DEFICIENCY						
GASTRITIS						
GENITAL DISCHARGE						
HEADACHE						
HERPES DERMATITIS						
HOT FLUSH						
HYPERCOAGULATION						
HYPERHIDROSIS						
HYPERSENSITIVITY						
HYPOTENSION						
IMPAIRED WORK ABILITY						
INFECTIOUS MONONUCLEOSIS						
INFLUENZA LIKE ILLNESS						
INSOMNIA						
INTERNATIONAL NORMALISED RATIO DECREASED						
INTERNATIONAL NORMALISED RATIO INCREASED						
IRITIS						
IRON DEFICIENCY ANAEMIA						
IRRITABLE BOWEL SYNDROME						
JOINT SWELLING						
LABYRINTHITIS						
LISTLESS						
LOSS OF LIBIDO						
LOWER RESPIRATORY TRACT INFECTION VIRAL						
LYMPHADENOPATHY						
LYMPHOEDEMA						
MAJOR DEPRESSION						
MALAISE						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MASTOPTOSIS						
MEMORY IMPAIRMENT						
MENIERE'S DISEASE						
MENORRHAGIA						
METRORRHAGIA						
MIGRAINE						
MIGRAINE WITH AURA						
MOOD SWINGS						
MULTIPLE INJURIES						
MUSCLE SPASMS						
MUSCLE STRAIN						
MUSCULOSKELETAL CHEST PAIN						
MYOSITIS						
NAUSEA						
NECK PAIN						
NIGHTMARE						
OEDEMA PERIPHERAL						
ONYCHOCLASIS						
OSTEOARTHRITIS						
OVARIAN CYST						
PAIN						
PAIN IN EXTREMITY						
PARAESTHESIA						
PELVIC PAIN						
PHARYNGITIS						
POLLAKIURIA						
PREMENSTRUAL SYNDROME						
PROCTALGIA						
PROTEIN C DECREASED						
RASH						
SEDATION						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SLEEP APNOEA SYNDROME						
SLEEP DISORDER						
SNORING						
SOMNOLENCE						
SUICIDAL IDEATION						
SYSTEMIC LUPUS ERYTHEMATOSUS						
TENSION HEADACHE						
THROMBOSIS						
TINNITUS						
TRICUSPID VALVE INCOMPETENCE						
URINARY TRACT INFECTION						
UTERINE LEIOMYOMA						
VAGINITIS BACTERIAL						
VERTIGO POSITIONAL						
VIRAL INFECTION						
VITAMIN B12 DEFICIENCY						
VITAMIN D DEFICIENCY						
VOMITING						
VULVOVAGINAL MYCOTIC INFECTION						
WEIGHT DECREASED						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-May-2012	8559282	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030352	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINA BIFIDA	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-May-2012	8441533	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2012054125		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BIPOLAR DISORDER	LIPITOR	S		80 mg, daily		PFIZER
PYREXIA	LIPITOR	S				PFIZER
HYPERSENSITIVITY	NITROSTAT	S		UNK		PFIZER
WEIGHT DECREASED	XANAX	S		UNK		PFIZER
EATING DISORDER	ALPRAZOLAM	S		UNK		PFIZER
HEADACHE	CARVEDILOL	S		UNK		
ARTHRALGIA	ESCITALOPRAM OXALATE	S		UNK		
DRUG INTOLERANCE	LEXAPRO	S		UNK		
INFLUENZA LIKE ILLNESS	NITROSTAT	C		UNK		
DIARRHOEA	ASPIRIN	C		81 mg, UNK		
BACK PAIN	QUINAPRIL	C		UNK, daily		
NECK PAIN	XANAX	C		2 mg, 3x/day		
PAIN IN EXTREMITY	COREG	C		25 mg, UNK		
	PLAVIX	C		75 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-May-2012	8475062	EXPEDITED (15-DAY)	N	HO,CA,OT	US-FRI-1000029169		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TRANSPOSITION OF THE GREAT VESSELS	LEXAPRO	S	TRANSPLACENTAL			
PYLORIC STENOSIS	PROZAC	C				
CEREBRAL HAEMORRHAGE NEONATAL	NATACHEW	C				
FOETAL EXPOSURE DURING PREGNANCY	ESGIC-PLUS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-May-2012	8498399	EXPEDITED (15-DAY)	N	OT	US-FRI-1000029168	27 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GESTATIONAL HYPERTENSION	LEXAPRO	S	ORAL			
MATERNAL EXPOSURE DURING PREGNANCY	PROZAC	C	ORAL	10 mg		
	NATACHEW	C	ORAL	1 mg		
	ESGIC-PLUS	C	ORAL	500 mg/50 mg/40 mg Q6H		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-May-2012	8491744	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000029494		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEPATIC FUNCTION ABNORMAL	LEXAPRO	S	ORAL	10 mg		
	PRAVASTATIN SODIUM	S		1 DF		
	LANSOPRAZOLE	C	ORAL	30 mg		
	BROTIZOLAM	C	ORAL	0.25 mg		
	FLUNITRAZEPAM	C	ORAL	4 mg		
	NITRAZEPAM	C	ORAL	10 mg		
	SEROQUEL	C	ORAL	700 mg		
	LITHIUM CARBONATE	C	ORAL	600 mg		
	MAGTECT	C	ORAL	35 ml		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-May-2012	8530636	EXPEDITED (15-DAY)	Y	HO	JP-FRI-1000030013	74 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ENTEROCOLITIS	LEXAPRO	S		10 mg		
POLLAKIURIA	AMLODIPINE	C	ORAL	5 mg		
ABDOMINAL DISTENSION	CANDESARTAN CILEXETIL	C	ORAL	4 mg		
NAUSEA	AMARYL	C	ORAL	1 mg		
	ACTOS	C	ORAL	15 mg		
	BIOFERMIN	C	ORAL	3 g		
	LAC-B	C	ORAL	3 g		
	RHUBARB	C	ORAL	0.5 g		
	MIGLITOL	C	ORAL	150 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-May-2012	8567205	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0973648A	75 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MALAISE	VOTRIENT	S	ORAL	800MGD per day		GLAXOSMITHKLINE
VOMITING	LEXAPRO	S				
	TUMS	C				GLAXOSMITHKLINE

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-May-2012	7775716	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-US-WYE-H11674109	74 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	EFFEXOR XR	S	ORAL	75 mg, 1x/day		PFIZER
SUICIDAL IDEATION	PRISTIQ EXTENDED RELEASE	S	ORAL	50 mg, 1x/day		PFIZER
DIARRHOEA	PRISTIQ EXTENDED RELEASE	S	ORAL	half a tablet		PFIZER
DYSKINESIA	DOXEPIN HYDROCHLORIDE	S		UNK		PFIZER
TREMOR	ZOLOFT	S		UNK		PFIZER
MUSCLE TWITCHING	MIRTAZAPINE	S		UNK		
NIGHTMARE	PAROXETINE	S		UNK		
DRUG INEFFECTIVE	TRAZODONE	S		UNK		
DRUG EFFECT DECREASED	WELLBUTRIN	S		UNK		
DRY MOUTH	ZYPREXA	S		UNK		
AGEUSIA	SEROQUEL	S		UNK		
CONSTIPATION	LEXAPRO	S		UNK		
DECREASED APPETITE	CYMBALTA	S		UNK		
	PAXIL	S		UNK		
	PROZAC	S		UNK		
	DEPAKOTE	S		UNK		
	ONE-A-DAY NOS	C				
	FISH OIL, HYDROGENATED	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-May-2012	8569700	EXPEDITED (15-DAY)	Y	HO	US-FRI-1000030433	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MENTAL DISORDER	LEXAPRO	S		10 mg		
MALAISE	XANAX XR	S	ORAL	3 mg		
	XANAX XR	S				
	XANAX XR	S				
	LIPITOR	C		10 mg		

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2012	7932083	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2011-01248	75 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG EFFECT DECREASED	MIRTAZAPINE	S				
DRUG INEFFECTIVE	PAROXETINE HYDROCHLORIDE	S				
DIARRHOEA	PRISTIQ EXTENDED RELEASE	S	ORAL	50 MG (50 MG, 1 IN 1 D), ORAL; PATIENT TRIED TAKING HALF A TABLET, ORAL		
SUICIDAL IDEATION	EFFEXOR XR	S	ORAL	75 MG (75 MG, 1 IN 1 D), ORAL		
SUICIDE ATTEMPT	DOXEPIN HYDROCHLORIDE	S				
TREMOR	ZOLOFT	S				
MUSCLE TWITCHING	TRAZODONE HYDROCHLORIDE	S				
NIGHTMARE	WELLBUTRIN	S				
	SEROQUEL	S				
	LEXAPRO	S				
	CYMBALTA	S				
	PROZAC	S				
	DEPAKOTE	S				
	PAXIL	S				
	ZYPREXA	C				
	ONE-A-DAY	C				
	FISH OIL, HYDROGENATED	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2012	8545220	EXPEDITED (15-DAY)	N	OT	CN-JNJFOC-20110406144	16 YR	Female	CHN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC ENZYMES INCREASED	INVEGA	S	ORAL			
ASTHENIA	RISPERDAL	S	ORAL	0.5 mg in the morning and 1 mg at night		
INFLUENZA LIKE ILLNESS	LEXAPRO	S	ORAL			
SOMNOLENCE	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2012	8554570	EXPEDITED (15-DAY)	Y	OT	AU-FRI-1000030359		Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MULTIPLE SCLEROSIS	LEXAPRO	S	ORAL	10 mg		
OFF LABEL USE	NASONEX	C				
	PANVAX	C				
	CEFACLOR	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2012	8590406	DIRECT	N			49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	LEXAPRO	S		15MG/DAY		MYLAN
DEPRESSION						
DISEASE RECURRENCE						
PRODUCT SUBSTITUTION ISSUE						
WITHDRAWAL SYNDROME						

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-May-2012	8602264	DIRECT	Y	OT		31 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INEFFECTIVE	LEXAPRO	S		20 MG 1 DLY		
ANXIETY						
CONDITION AGGRAVATED						
DEPRESSION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-May-2012	8505242	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20120404439		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CEREBROVASCULAR ACCIDENT	TRAMADOL HYDROCHLORIDE	S	UNKNOWN			
MUSCLE SPASTICITY	WELLBUTRIN	S	ORAL			
MUSCULOSKELETAL STIFFNESS	LEXAPRO	S	UNKNOWN			
PAIN	CYMBALTA	S	ORAL			
HYPERTENSION	UNSPECIFIED INGREDIENT	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-May-2012	8583594	EXPEDITED (15-DAY)	Y	HO,OT	AU-ASTRAZENECA-2012SE32165	< 1 DAY	Male	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME NEONATAL	SEROQUEL XR	S	TRANSPLACENTAL	75-100 MG DAILY STARTED PRE-PREGNANCY AND STOPPED AFTER DELIVERY		ASTRAZENECA
MECONIUM ABNORMAL	LEXAPRO	S	TRANSPLACENTAL	20MG DAILY STARTED AT 16/40 WEEKS AND STOPPED AFTER DELIVERY		
	DEXTROAMPHETAMINE	S	TRANSPLACENTAL	10MG AS REQUIRED STARTED PRE-PREGNANCY UNTIL 35/40 WEEKS		
	DEXAMETHASONE	C	TRANSPLACENTAL	10MG AS REQUIRED STARTED PRE-PREGNANCY AND STOPPED AT 35/40 WEEKS		
	AMINOBENZOIC ACID\BIOTIN\CHOLINE\FOLIC ACID\INOSITOL	C	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-May-2012	8584787	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000030783	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GASTROINTESTINAL INFLAMMATION	LEXAPRO	S		20 mg		
NAUSEA	LEXAPRO	S			10 YR	
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-May-2012	8585901	EXPEDITED (15-DAY)	Y	HO	AU-FRI-1000030789	23 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GALACTORRHOEA	LEXAPRO	S	ORAL	10 mg		
BREAST DISCHARGE						
BREAST PAIN						
BREAST SWELLING						
DEPRESSION						
PSYCHOMOTOR HYPERACTIVITY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8588723	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030913	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COARCTATION OF THE AORTA	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8588777	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030911	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			
PATENT DUCTUS ARTERIOSUS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8588813	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030909	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOPLASTIC LEFT HEART SYNDROME	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8588830	EXPEDITED (15-DAY)	N	DE	US-FRI-1000030907	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC DISORDER	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8588848	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030855	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOPLASTIC LEFT HEART SYNDROME	LEXAPRO	S	TRANSPLACENTAL			
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8588850	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030905	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8588882	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030901	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOPLASTIC LEFT HEART SYNDROME	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8589063	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030863	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOPLASTIC LEFT HEART SYNDROME	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8589269	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030899	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			
AORTIC VALVE PROLAPSE						
CONGENITAL AORTIC VALVE INCOMPETENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8589308	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030897	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TRANSPOSITION OF THE GREAT VESSELS	LEXAPRO	S	TRANSPLACENTAL			
ATRIAL SEPTAL DEFECT						
NEONATAL CARDIAC FAILURE						
PULMONARY ARTERY STENOSIS CONGENITAL						
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8589373	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030895	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PATENT DUCTUS ARTERIOSUS	LEXAPRO	S	TRANSPLACENTAL			
ATRIAL SEPTAL DEFECT						
PULMONARY ARTERY STENOSIS CONGENITAL						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8589448	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030877	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPOPLASTIC LEFT HEART SYNDROME	LEXAPRO	S	TRANSPLACENTAL			
BICUSPID AORTIC VALVE						
COARCTATION OF THE AORTA						
PATENT DUCTUS ARTERIOSUS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8589483	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030865	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEART DISEASE CONGENITAL	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8589522	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030867	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COARCTATION OF THE AORTA	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8589549	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030869	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FALLOT'S TETRALOGY	LEXAPRO	S	TRANSPLACENTAL			
ATRIAL SEPTAL DEFECT						
PULMONARY ARTERY STENOSIS CONGENITAL						
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2012	8607666	DIRECT	Y			60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERTHERMIA	TRAZODONE HYDROCHLORIDE	S				
DYSPNOEA	LEXAPRO	S				
CHROMATOPSIA						
FAECAL INCONTINENCE						
LOSS OF CONSCIOUSNESS						
SEROTONIN SYNDROME						
URINARY INCONTINENCE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2012	8590463	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030871	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2012	8590486	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030873	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FALLOT'S TETRALOGY	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2012	8590651	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030875	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			
ATRIAL SEPTAL DEFECT						
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2012	8590756	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030879	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TRANSPOSITION OF THE GREAT VESSELS	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2012	8590881	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030881	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2012	8590950	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030883	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIOVENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2012	8590951	EXPEDITED (15-DAY)	N	DE	US-FRI-1000030885		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC DISORDER	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2012	8590979	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030887	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PATENT DUCTUS ARTERIOSUS ATRIAL SEPTAL DEFECT VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2012	8591063	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030889	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TRANSPOSITION OF THE GREAT VESSELS	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2012	8591174	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030891	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FALLOT'S TETRALOGY DOUBLE OUTLET RIGHT VENTRICLE PULMONARY ARTERY STENOSIS CONGENITAL VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2012	8591214	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030893	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FALLOT'S TETRALOGY	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jun-2012	8591244	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030903	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TRANSPOSITION OF THE GREAT VESSELS	LEXAPRO	S	TRANSPLACENTAL			
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jun-2012	7183450	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-US-WYE-H11366009	74 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	EFFEXOR XR	S	ORAL	75 mg, 1x/day		PFIZER
SUICIDE ATTEMPT	PRISTIQ EXTENDED RELEASE	S	ORAL	50.0 mg, 1x/day		PFIZER
DIARRHOEA	PRISTIQ EXTENDED RELEASE	S	ORAL	Patient tried taking half a tablet		PFIZER
DYSKINESIA	DOXEPIN HYDROCHLORIDE	S		UNK		PFIZER
TREMOR	ZOLOFT	S		UNK		PFIZER
MUSCLE TWITCHING	MIRTAZAPINE	S		UNK		
NIGHTMARE	PAROXETINE	S		UNK		
DRUG INEFFECTIVE	TRAZODONE HYDROCHLORIDE	S		UNK		
DRUG EFFECT DECREASED	WELLBUTRIN	S		UNK		
DRY MOUTH	ZYPREXA	S		UNK		
AGEUSIA	SEROQUEL	S		UNK		
CONSTIPATION	LEXAPRO	S		UNK		
DECREASED APPETITE	CYMBALTA	S		UNK		
	PAXIL	S		UNK		
	PROZAC	S		UNK		
	DEPAKOTE	S		UNK		
	ONE-A-DAY NOS	C				
	FISH OIL, HYDROGENATED	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jun-2012	8598598	NON-EXPEDITED	Y	OT	US-FRI-1000030775	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Candida infection	LEXAPRO	S	ORAL			
	BYSTOLIC	C				
	SYNTHROID	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jun-2012	8600191	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2012131172	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
COGNITIVE DISORDER	PRISTIQ EXTENDED RELEASE	S		100 mg, UNK		PFIZER
SUICIDAL IDEATION	PRISTIQ EXTENDED RELEASE	S				PFIZER
HALLUCINATION	PRISTIQ EXTENDED RELEASE	S				PFIZER
DRUG INEFFECTIVE	EFFEXOR XR	S		UNK		PFIZER
WEIGHT INCREASED	XANAX	S		UNK		PFIZER
MIGRAINE	LEXAPRO	S		UNK		
SWELLING	PROZAC	S		UNK		
FLUID RETENTION	WELLBUTRIN	S		UNK		
NAUSEA	CYMBALTA	S		UNK		
DIZZINESS	LISINOPRIL	C		10 mg, UNK		
BLOOD GLUCOSE INCREASED						
BLOOD TRIGLYCERIDES INCREASED						
HIGH DENSITY LIPOPROTEIN INCREASED						
LOW DENSITY LIPOPROTEIN INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jun-2012	8623471	DIRECT	N				Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANXIETY	LEXAPRO	S				TEVA
PRURITUS GENERALISED	ESCITALOPRAM OXALATE	C				
ABNORMAL DREAMS						
AGITATION						
ANGER						
BLOOD PRESSURE INCREASED						
HYPERACUSIS						
INSOMNIA						
PRODUCT SUBSTITUTION ISSUE						
STRESS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jun-2012	8603685	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030965	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			
Maternal drugs affecting foetus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jun-2012	8603696	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030967		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CRANIOSYNOSTOSIS	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jun-2012	8603812	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030969		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CRANIOSYNOSTOSIS	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jun-2012	8635044	DIRECT	Y	OT		40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TREMOR	CITALOPRAM	S	ORAL	20 MG DAILY ORAL		FOREST
NAUSEA	LEXAPRO	S				
HEADACHE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jun-2012	8605324	EXPEDITED (15-DAY)	N	HO	US-FRI-1000030988	23 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PHYSICAL ASSAULT	LEXAPRO	S	ORAL	10 MG		
AGGRESSION	LEXAPRO	S	ORAL	20 MG		
AGITATION	RISPERDAL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jun-2012	8605803	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030999	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TALIPES	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jun-2012	8606101	EXPEDITED (15-DAY)	N	CA	US-FRI-1000031051		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CRANIOSYNOSTOSIS	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jun-2012	8527423	EXPEDITED (15-DAY)	Y	HO,OT	JP-FRI-1000029975	67 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEPATIC FUNCTION ABNORMAL	LEXAPRO	S	ORAL	10 mg		
JAUNDICE	PHENOBARBITAL	C	ORAL			
	BROMISOVAL	C	ORAL	0.3 mg		
	ALPRAZOLAM	C	ORAL	1.2 mg		
	SULPIRIDE	C	ORAL	150 mg		
	HANGE-KOBOKU-TO	C	ORAL	3 DF		
	FLUNITRAZEPAM	C	ORAL	2 mg		
	CHLORPROMAZINE HYDROCHLORIDE	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jun-2012	8608989	EXPEDITED (15-DAY)	Y	DS	AU-FRI-1000031167	63 YR	Male	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
WITHDRAWAL SYNDROME	LEXAPRO	S	ORAL	Overdose 40 mg - downtitrated		
OVERDOSE	PROTHIADEN	C		100 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jun-2012	8536309	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000030085	44 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ANAPHYLACTIC SHOCK	LEXAPRO	S	ORAL	10 mg		
	BIPERIDEN HYDROCHLORIDE	S	ORAL	3 mg		
	ETIZOLAM	C	ORAL			
	BROMAZEPAM	C	ORAL			
	ESTAZOLAM	C	ORAL	2 mg		
	ETIZOLAM	C	ORAL	3 mg		
	PAXIL	C	ORAL	20 mg		
	YORYACOOL	C	ORAL	160 mg		
	LOXOPROFEN SODIUM	C	ORAL	60 mg		
	MANIDIPINE HYDROCHLORIDE	C	ORAL	10 mg		
	AMOXAPINE	C	ORAL	75 mg		
	AMOXAPINE	C	ORAL	75 mg		
	MAGNESIUM OXIDE	C	ORAL	1980 mg		
	BROTIZOLAM	C	ORAL	0.25 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jun-2012	8613098	EXPEDITED (15-DAY)	N	CA	US-FRI-1000031170		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			
CARDIAC ANEURYSM						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jun-2012	8613397	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000025991		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION SUICIDAL	LEXAPRO	S				
STRESS	EFFEXOR	S				
	AMBIEN	S				
	ZYPREXA	S				
	WELLBUTRIN	S		600 mg		
	ADDERALL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jun-2012	8635091	DIRECT	Y	OT		45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG EFFECT DECREASED	LEXAPRO	S	ORAL	ONE PO QD		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jun-2012	8619769	EXPEDITED (15-DAY)	N	CA	US-FRI-1000031354		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CRANIOSYNOSTOSIS	LEXAPRO	S	TRANSPLACENTAL			
CONGENITAL ANOMALY						
DEVELOPMENTAL DELAY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jun-2012	8620578	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000031432	47 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSPNOEA	LEXAPRO	S	ORAL	10 mg		
CHILLS	LEXAPRO	S	ORAL	20 mg		
TREMOR	LORAZEPAM	C	ORAL	1.5 mg		
	ETHYL LOFLAZEPATE	C	ORAL	2 mg		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jun-2012	8622366	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000031238	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
THINKING ABNORMAL	LEXAPRO	S				
WEIGHT INCREASED	PRISTIQ EXTENDED RELEASE	S				
SUICIDAL IDEATION	PRISTIQ EXTENDED RELEASE	S				
SWELLING	PRISTIQ EXTENDED RELEASE	S				
FLUID RETENTION	EFFEXOR XR	S				
NAUSEA	XANAX	S				
HALLUCINATION	PROZAC	S				
DIZZINESS	WELLBUTRIN	S				
BLOOD GLUCOSE INCREASED	CYMBALTA	S				
HIGH DENSITY LIPOPROTEIN INCREASED	LISINOPRIL	C				
ABDOMINAL DISCOMFORT						
BLOOD TRIGLYCERIDES INCREASED						
DRUG INEFFECTIVE						
LOW DENSITY LIPOPROTEIN INCREASED						
MIGRAINE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jun-2012	7460252	EXPEDITED (15-DAY)	N	DE	US-MYLANLABS-2010S1011460	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TOXICITY TO VARIOUS AGENTS	FENTANYL TRANSDERMAL SYSTEM	S	TRANSDERMAL	Change q3d		
OVERDOSE	NORTRIPTYLINE HYDROCHLORIDE	S				
RESPIRATORY DEPRESSION	LEXAPRO	S				
	DIPHENHYDRAMINE	S				
	SYMBICORT	C	INHALATION			
	ADVAIR DISKUS	C				
	DIAZEPAM	C		Every 8 hours		
	DIOVAN	C				
	PLAVIX	C				
	LYRICA	C				
	IBUPROFEN	C		Every 4-6 hours		
	NEXIUM	C				
	METFORMIN HYDROCHLORIDE	C				
	GLYCOL SALICYLATE\MENTHOL\METHYL SALICYLATE\THYMOL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jun-2012	8541119	EXPEDITED (15-DAY)	Y	HO,OT	US-PFIZER INC-2012104183	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MENTAL DISORDER	XANAX XR	S	ORAL	1 mg, 3x/day		PFIZER
MALAISE	XANAX XR	S				PFIZER
DEPRESSION	XANAX XR	S				PFIZER
ANXIETY	XANAX XR	S				PFIZER
	LEXAPRO	S		20 mg, UNK		
	LEXAPRO	S		UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jun-2012	8628946	EXPEDITED (15-DAY)	N	HO	US-FRI-1000031418	96 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	LEXAPRO	S	ORAL	5 mg		
HOMICIDAL IDEATION						
OFF LABEL USE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jun-2012	8629283	EXPEDITED (15-DAY)	N	CA	US-FRI-1000031368	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			
ATRIAL SEPTAL DEFECT						
BICUSPID AORTIC VALVE						
CONGENITAL ANOMALY						
PULMONARY ARTERY STENOSIS						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2012	8630348	EXPEDITED (15-DAY)	Y	HO	JP-FRI-1000031510	69 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PNEUMONIA ASPIRATION	LEXAPRO	S	ORAL	10 mg		
VOMITING	LEXAPRO	S	ORAL	20 mg		
	REMERON	C	ORAL	45 mg		
	ETHYL LOFLAZEPATE	C	ORAL	45 mg		
	LANSOPRAZOLE	C	ORAL	15 mg		
	URAPIDIL	C	ORAL	60 mg		
	MAGNESIUM OXIDE	C	ORAL	2640 mg		
	ESTAZOLAM	C	ORAL	4 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jun-2012	8546091	NON-EXPEDITED	Y		US-PFIZER INC-2012104197		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING ABNORMAL	XANAX XR	S	ORAL	1 mg, 3x/day		PFIZER
ANXIETY	XANAX XR	S				PFIZER
FATIGUE	XANAX XR	S				PFIZER
ABDOMINAL DISCOMFORT	ALPRAZOLAM	S	ORAL	UNK		PFIZER
MALAISE	ALPRAZOLAM	S	ORAL	1 mg, 3x/day		PFIZER
DRUG INTOLERANCE	ALPRAZOLAM	S				PFIZER
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jun-2012	8645533	DIRECT					Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NO ADVERSE EVENT	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jun-2012	8636767	EXPEDITED (15-DAY)	Y	HO	US-FRI-1000031496	79 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MENTAL STATUS CHANGES	LEXAPRO	S	ORAL	10 mg		
DEHYDRATION	NAMENDA	S	ORAL	20 mg		
ANAEMIA	BAPINEUZUMAB	S	INTRAVENOUS			
DRUG INEFFECTIVE	BABY ASPIRIN	C	ORAL	81mg		
	OMEPRAZOLE	C	ORAL	20 mg		
	METFORMIN HYDROCHLORIDE	C	ORAL	1000 mg		
	SIMVASTATIN	C	ORAL	40 mg		
	RAMIPRIL	C	ORAL	2.5 mg		
	EXELON	C	TRANSDERMAL	9.5 mg		
	CENTRUM	C	ORAL	1 Dosage forms		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jun-2012	8636986	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000031578		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VISUAL ACUITY REDUCED	LEXAPRO	S	ORAL	20 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jun-2012	8639708	EXPEDITED (15-DAY)	N	OT	US-FRI-1000031555	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VENTRICULAR SEPTAL DEFECT ATRIAL SEPTAL DEFECT	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2012	8640875	EXPEDITED (15-DAY)	N	CA	US-FRI-1000031557	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL SEPTAL DEFECT Maternal drugs affecting foetus TRANSPOSITION OF THE GREAT VESSELS	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2012	8641063	EXPEDITED (15-DAY)	N	OT	US-FRI-1000031559	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TALIPES CONGENITAL ANOMALY	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2012	8661088	DIRECT		HO			Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION AUTONOMIC NERVOUS SYSTEM IMBALANCE	LEXAPRO	S		1 PILL 1 A DAY FOR 4 DAYS		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Jul-2012	8648757	EXPEDITED (15-DAY)	N	CA	US-FRI-1000036707	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINA BIFIDA HYDROCEPHALUS	LEXAPRO	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jul-2012	8612752	NON-EXPEDITED	N		US-PFIZER INC-2012139829		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG HYPERSENSITIVITY	LYRICA	S		UNK		PFIZER
	ATARAX	S		UNK		PFIZER
	BYSTOLIC	S		UNK		
	TRAZODONE HYDROCHLORIDE	S		UNK		
	ELAVIL	S		UNK		
	LEXAPRO	S		UNK		
	WELLBUTRIN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jul-2012	8650472	NON-EXPEDITED	Y		US-PFIZER INC-2012157422		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING DRUNK	LYRICA	S		UNK		PFIZER
	HYDROXYZINE HYDROCHLORIDE	S		UNK		PFIZER
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jul-2012	8650979	EXPEDITED (15-DAY)	N	CA	US-FRI-1000036768	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SPINA BIFIDA	LEXAPRO	S	TRANSPLACENTAL			
ARNOLD-CHIARI MALFORMATION						
CONGENITAL ANOMALY						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jul-2012	8666057	DIRECT	Y	HO		55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPONATRAEMIA	LEXAPRO	S	ORAL	ONE TABLET DAILY PO		
DYSPNOEA						
WHEEZING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jul-2012	8651858	NON-EXPEDITED	N		US-FRI-1000036800	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PARAESTHESIA	LEXAPRO	S	ORAL	10 mg		
IRRITABILITY	LEXAPRO	S	ORAL	20 mg		
DEPRESSION	CLONIDINE	C				
CRYING	POTASSIUM	C				
	VITAMIN B1	C				
	FOLIC ACID	C				
	LOSARTAN POTASSIUM	C				
	SUBOXONE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jul-2012	8651886	NON-EXPEDITED	Y		US-FRI-1000036806		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING JITTERY	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2012	8670084	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FATIGUE	LEXAPRO	S				FOREST
FEELING ABNORMAL	ESTRADIOL	C				
DECREASED APPETITE	VITAMIN B12 1000 MG	C				
DRUG INEFFECTIVE						
MOVEMENT DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2012	8671705	DIRECT	N				Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRODUCT SUBSTITUTION ISSUE	LEXAPRO	S	ORAL	10 MG ONCE PO QD		
DRUG INEFFECTIVE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2012	8673906	DIRECT				87 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
MEDICATION ERROR	LEXAPRO	S				
AGITATION						
DISORIENTATION						
FALL						
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION						
MENTAL STATUS CHANGES						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2012	8673975	DIRECT				18 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
INTERCEPTED DRUG DISPENSING ERROR	LISINOPRIL	S		10 MG		
	LEXAPRO	S		10 MG		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jul-2012	8648613	EXPEDITED (15-DAY)		HO	US-FRI-1000036747	29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CHOLECYSTITIS	LEXAPRO	S	ORAL	20 mg		
CHOLELITHIASIS	UNSPECIFIED INGREDIENT	S	ORAL	3 mg		
	YASMIN	C				
	BIOTENE	C				
	ZYRTEC	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jul-2012	8658815	EXPEDITED (15-DAY)	Y	DE	JP-FRI-1000036917		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEATH	LEXAPRO	S	ORAL			
	ADALAT	C	ORAL			
	BROTIZOLAM	C	ORAL			
	NEUROTROPIN NEUROTROPIN (AN EXTRACT OBTAINED FROM INFLAMMATORY RABBIT S	C	ORAL			
	NICORANDIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jul-2012	8673970	DIRECT	Y			63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PRODUCT SUBSTITUTION ISSUE	LEXAPRO	S	ORAL	LEXAPRO 10MG QD ORAL		
DRUG INEFFECTIVE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jul-2012	8660829	EXPEDITED (15-DAY)	Y	HO	AU-FRI-1000036940	< 1 DAY	Male	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG WITHDRAWAL SYNDROME NEONATAL	LEXAPRO	S	TRANSPLACENTAL	20 mg		
FOETAL EXPOSURE DURING PREGNANCY	DEXAMPHETAMINE	C	TRANSPLACENTAL	20 mg		
	QUETIAPINE	C	TRANSPLACENTAL	75 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jul-2012	8662137	NON-EXPEDITED			US-MUTUAL PHARMACEUTICAL COMPANY, INC.-IMPR20110002	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ABNORMAL DREAMS	IMIPRAMINE HYDROCHLORIDE	S	ORAL			MUTUAL
DRUG WITHDRAWAL SYNDROME	IMIPRAMINE HYDROCHLORIDE	S	ORAL			MUTUAL
DRUG INEFFECTIVE	IMIPRAMINE HYDROCHLORIDE	S	ORAL			MUTUAL
OFF LABEL USE	IMIPRAMINE HYDROCHLORIDE	S				MUTUAL
ANXIETY	LEXAPRO	S	ORAL			
DEPRESSION	LEXAPRO	S				
HEADACHE	CLONAZEPAM	C	ORAL			
	BENAZEPRIL	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jul-2012	8677612	DIRECT	N	DS		39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DYSPHEMIA	ABILIFY	S	ORAL	PO COUPLE MONTHS		
AKATHISIA	LEXAPRO	S	ORAL	PO COUPLE MONTHS		
GAIT DISTURBANCE						
MUSCLE TWITCHING						
SPEECH DISORDER						
TIC						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Jul-2012	8639288	EXPEDITED (15-DAY)	Y	DE,HO,LT	JP-FRI-1000036599	66 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
PNEUMONIA	LEXAPRO	S	ORAL	10 mg		
ALTERED STATE OF CONSCIOUSNESS	PROMAZINE HYDROCHLORIDE	C	ORAL			
	NESINA	C	ORAL	25 mg		
	LANSOPRAZOLE	C	ORAL			
	ETIZOLAM	C	ORAL	1 mg		
	FLUNITRAZEPAM	C	ORAL	2 mg		
	TRAZODONE HYDROCHLORIDE	C	ORAL	50 mg		
	CLONAZEPAM	C	ORAL	0.5 mg		
	BAYASPIRIN	C	ORAL	100 mg		
	METFORMIN HYDROCHLORIDE	C	ORAL	750 mg		
	MIRTAZAPINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jul-2012	8671443	EXPEDITED (15-DAY)	N	CA	US-FRI-1000036985	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CLEFT LIP	LEXAPRO	S	TRANSPLACENTAL			
CONGENITAL ANOMALY						
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jul-2012	8696220	DIRECT	N	LT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERTENSION	LEXAPRO	S			3 MTH	
BLOOD CHOLESTEROL INCREASED	CYMBALTA	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2012	8488077	EXPEDITED (15-DAY)	Y	HO	AU-FRI-1000029481	63 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
EPISTAXIS	LEXAPRO	S	ORAL	Prescribed overdose: 50 mg daily		
OVERDOSE	OXAZEPAM	C				
	MIRTAZAPINE	C				
	LORAZEPAM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2012	8661501	EXPEDITED (15-DAY)	Y	OT	JP-PFIZER INC-2012165348		Unknown	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYPERVENTILATION	ATARAX	S	INTRAMUSCULAR			PFIZER
OXYGEN SATURATION DECREASED	ZOLOFT	S	ORAL			PFIZER
	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jul-2012	8671769	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000037172	50 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 mg		
	LEXAPRO	S	ORAL	5 mg		
	ZOLOFT	C	ORAL	50 mg		
	ZOLOFT	C	ORAL	75 mg		
	ZOLOFT	C	ORAL	100 mg		
	ZOLOFT	C	ORAL	50 mg		
	ZOLOFT	C	ORAL	25 mg		
	SULPIRIDE	C	ORAL	150 mg		
	SULPIRIDE	C	ORAL	100 mg		
	SULPIRIDE	C	ORAL	75 mg		
	SULPIRIDE	C	ORAL	50 mg		
	PALGIN	C	ORAL	0.5 mg		
	MYSLEE	C	ORAL	10 mg		
	FLUNITRAZEPAM	C	ORAL	2 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jul-2012	8678777	EXPEDITED (15-DAY)	Y	HO	NL-FRI-1000037259	45 YR	Female	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Jaw fracture	LEXAPRO	S	ORAL	18 mg		
	ETHINYL ESTRADIOL	C	ORAL			
	FEXOFENADINE	C	ORAL	270 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Jul-2012	8680277	NON-EXPEDITED	N		US-BAYER-2012-073352		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
THERAPEUTIC RESPONSE UNEXPECTED	LEVITRA	S		UNK		
	LEXAPRO	S		UNK		
	ADDERALL XR	S		UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jul-2012	8687373	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000037225		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
UNEVALUABLE EVENT	LEXAPRO	S				
FEELING ABNORMAL	RAMIPRIL	C				
ANXIETY	ESTRADIOL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jul-2012	8690526	NON-EXPEDITED	N	OT	US-ASTRAZENECA-2012SE 18514	48 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	SEROQUEL	S	ORAL			ZENECA
MOOD SWINGS	SEROQUEL	S	ORAL			ZENECA
PARANOIA	PRISTIQ EXTENDED RELEASE	S				
INSOMNIA	WELLBUTRIN	S				
DRUG INEFFECTIVE	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jul-2012	8710335	DIRECT	Y			43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTOLERANCE	LEXAPRO	S	ORAL	40 MG LEXAPRO QD PO		
DEPRESSIVE SYMPTOM						
DISEASE RECURRENCE						
PRODUCT SUBSTITUTION ISSUE						
SEDATION						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jul-2012	8712867	DIRECT	N	LT,OT		43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FEELING ABNORMAL	LEXAPRO	S	ORAL	10 MG ONCE A DAY, PO	1 WEEK	FOREST
SUICIDAL IDEATION						
THOUGHT BLOCKING						
VITAMIN D						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jul-2012	8441197	EXPEDITED (15-DAY)	N	HO	US-FRI-1000028731	14 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDE ATTEMPT	LEXAPRO	S	ORAL	5 mg		
SUICIDAL IDEATION	LEXAPRO	S	ORAL	10 mg		
INTENTIONAL SELF-INJURY	LEXAPRO	S		5 mg		
DEPRESSION						
FATIGUE						
OFF LABEL USE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jul-2012	8691445	NON-EXPEDITED	Y		US-PFIZER INC-2012180587		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG HYPERSENSITIVITY	BEXTRA	S		UNK		PFIZER
ABDOMINAL DISCOMFORT	FLUOXETINE HCL	S		UNK		
PAIN	LEXAPRO	S		UNK		
	AMILORIDE HCL W/ HYDROCHLOROTHIAZIDE	S		UNK		
	BUPROPION	S		UNK		
	DICLOXACILLIN SODIUM	S		UNK		
	VICODIN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Jul-2012	8651153	EXPEDITED (15-DAY)	N	CA	US-FRI-1000036740	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TRANSPOSITION OF THE GREAT VESSELS	LEXAPRO	S	TRANSPLACENTAL			
DOUBLE OUTLET RIGHT VENTRICLE						
PULMONARY VALVE STENOSIS						
VENTRICULAR SEPTAL DEFECT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Jul-2012	8674205	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000037220	33 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ACTIVATION SYNDROME	LEXAPRO	S	ORAL	20 mg		
	LEXAPRO	S	ORAL	10 mg		
	VEGETAMIN-B	C	ORAL	1 DF		
	FLUNITRAZEPAM	C	ORAL	2 mg		
	ETIZOLAM	C	ORAL	1 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Aug-2012	8470615	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000029233	25 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONVULSION	LEXAPRO	S	ORAL	10 mg		
TREMOR	RILMAZAFONE HYDROCHLORIDE	S	ORAL			
ANXIETY						
DYSPHONIA						
FEAR						
VOMITING						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Aug-2012	8691538	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2011102419		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUICIDAL IDEATION	CHANTIX	S		0.5 mg, daily		PFIZER
URINARY RETENTION	CHANTIX	S		UNK		PFIZER
POLLAKIURIA	CHANTIX	S		1 mg, 2x/day		PFIZER
LOSS OF LIBIDO	GEODON	S		40 mg, 2x/day		PFIZER
INSOMNIA	ABILIFY	S		10 mg, daily		
THIRST	ABILIFY	S		15 mg, daily		
DRUG INEFFECTIVE	LEXAPRO	S		10 mg, UNK		
EJACULATION FAILURE	XANAX	C		UNK		
DRUG WITHDRAWAL SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Aug-2012	8696346	NON-EXPEDITED	N	OT	US-PFIZER INC-2012182500		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DEPRESSION	GEODON	S	ORAL	40 mg in morning and 80 mg at night		PFIZER
MUSCLE RIGIDITY	GEODON	S	ORAL	80 mg in morning and 80 mg at night		PFIZER
ANXIETY	GEODON	S	ORAL	80 mg at night and 20 mg in morning		PFIZER
HYPERSENSITIVITY	LEXAPRO	S		5 mg, Daily		
FATIGUE	LEXAPRO	S		10 mg, Daily		
WEIGHT INCREASED	LEXAPRO	S		20 mg, Daily		
	LEXAPRO	S		5 mg, Daily		
	DEPAKOTE	S		500 mg in morning and 1000 mg at night		
	RITALIN	C	ORAL	UNK		
	SEROQUEL	C		200 mg, daily		
	LAMICTAL	C		100 or 200 mg daily		
	AMBIEN	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Aug-2012	8726010	DIRECT	Y			48 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SCREAMING	LEXAPRO	S	ORAL	20 MG 1 PO AD		
PRODUCT SUBSTITUTION ISSUE						
VOMITING						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Aug-2012	8707202	EXPEDITED (15-DAY)	N	CA	US-FRI-1000037474	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HYDROCEPHALUS	LEXAPRO	S	TRANSPLACENTAL			
Maternal drugs affecting foetus						
MICROCEPHALY						
OCULOAURICULOVERTEBRAL DYSPLASIA						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Aug-2012	8476913	EXPEDITED (15-DAY)	Y	HO,OT	JP-FRI-1000029337	49 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
FACE OEDEMA	LEXAPRO	S	ORAL			
ABDOMINAL DISCOMFORT						
ABDOMINAL PAIN						
ALANINE AMINOTRANSFERASE INCREASED						
ASPARTATE AMINOTRANSFERASE INCREASED						
BLOOD PRESSURE INCREASED						
BLOOD URIC ACID INCREASED						
DIARRHOEA						
ELECTROCARDIOGRAM ABNORMAL						
EPISTAXIS						
GAMMA-GLUTAMYLTRANSFERASE INCREASED						
HYPERHIDROSIS						
MALAISE						
MUSCULOSKELETAL STIFFNESS						
MYALGIA						
NAUSEA						
OLIGURIA						
PHOTOPHOBIA						
POLLAKIURIA						
URINARY RETENTION						
VISUAL ACUITY REDUCED						
VOMITING						
WEIGHT INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Aug-2012	8731369	DIRECT	N	HO		70 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ATRIAL FIBRILLATION	LEXAPRO	S	ORAL	10MG 1/DAY PO		
	PRISTIQ EXTENDED RELEASE	S	ORAL	50MG 1/DAY PO		
	TENORMIN	C				
	PRADAXA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Aug-2012	8730603	DIRECT	Y	OT		61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
OEDEMA PERIPHERAL	LEXAPRO	S				MYLAN
AFFECTIVE DISORDER						
DIARRHOEA						
DRUG INTOLERANCE						
MENTAL DISORDER						
PRODUCT SUBSTITUTION ISSUE						
RENAL IMPAIRMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Aug-2012	8731409	DIRECT	N	DS			Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HEART DISEASE CONGENITAL	LEXAPRO	S	ORAL	10 MG 1X DAY ORAL		
EXPOSURE VIA FATHER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Aug-2012	8650960	EXPEDITED (15-DAY)	Y		US-JNJFOC-20120603399	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SOMNOLENCE	INVEGA	S	ORAL			
DEPRESSION	INVEGA	S	ORAL			
	INVEGA	S	ORAL			
	LEXAPRO	S	ORAL			
	XANAX	C	ORAL			
	GABAPENTIN	C	ORAL			
	UNKNOWN MEDICATION	C	UNKNOWN			
	ABILIFY	C	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Aug-2012	8731783	DIRECT	Y			14 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
GAZE PALSY	LEXAPRO	S	ORAL	1 1/2 PILLS PER DAY PO		
DYSKINESIA						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Aug-2012	8717403	EXPEDITED (15-DAY)	Y	HO	CN-FRI-1000037657	29 YR	Female	CHN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
JAUNDICE	LEXAPRO	S	ORAL	10 mg		
ASPARTATE AMINOTRANSFERASE INCREASED	JINGWU CAPSULES	C	ORAL	18 capsules		
ALANINE AMINOTRANSFERASE INCREASED	TONGTIAN ORAL SOLUTION	C	ORAL	30 ml		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Aug-2012	8677278	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20120706102	74 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONFUSIONAL STATE	ZYTIGA	S	ORAL			
HYPOKINESIA	LEXAPRO	S	ORAL			
DYSPNOEA EXERTIONAL	LEXAPRO	S	ORAL			
DEPRESSION	PREDNISONE	S	ORAL			
WEIGHT INCREASED	PREDNISONE	S	ORAL			
DIZZINESS						
FATIGUE						
FEAR						
HEADACHE						
HYPERSOMNIA						
MUSCULAR WEAKNESS						
OEDEMA PERIPHERAL						
PAIN						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2012	7923108	EXPEDITED (15-DAY)		OT	US-ASTRAZENECA-2010SE21304	68 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BREAST CANCER FEMALE	NEXIUM	S	ORAL			
PAIN IN EXTREMITY	CRESTOR	S	ORAL			
Meniscus injury	SYNTHROID	S	UNKNOWN			
THYROID DISORDER	LEXAPRO	S	UNKNOWN			
GASTROOESOPHAGEAL REFLUX DISEASE	ARIMIDEX	C				
ANXIETY						
PANIC ATTACK						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2012	8658256	EXPEDITED (15-DAY)	Y	HO,OT	JP-FRI-1000036745	68 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
ACTIVATION SYNDROME	LEXAPRO	S	ORAL	10 mg		
HYPERHIDROSIS	AMOXAPINE	C				
PALPITATIONS	OTHER SSRIS	C				
TREMOR	LUDIOMIL	C	ORAL			
BLOOD PRESSURE INCREASED						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2012	8723436	EXPEDITED (15-DAY)	N	OT	US-FRI-1000037812	79 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
TOXICITY TO VARIOUS AGENTS	LEXAPRO	S	ORAL	20 mg		
HALLUCINATION, AUDITORY	OXYCONTIN	S				
HALLUCINATION, VISUAL	OXYCONTIN	S		40 mg every 8 hours as needed		
DRUG INTERACTION	MORPHINE	S				
SOMNOLENCE	LUNESTA	S		3 mg		
CRYING	VICODIN	C		as needed		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2012	8749139	DIRECT	N	OT			Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DIARRHOEA	LEXAPRO	S	ORAL	10 MG, 1XDAY, PO	6 WEEK	
	PRISTIQ EXTENDED RELEASE	C				
	ZOLOFT	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Aug-2012	8686829	NON-EXPEDITED	Y		US-PFIZER INC-2012181543	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
NAUSEA	PRISTIQ EXTENDED RELEASE	S	ORAL	50 mg, 1x/day, at bedtime		PFIZER
	PRISTIQ EXTENDED RELEASE	S	ORAL	UNK		PFIZER
	LEXAPRO	S		UNK		
	EFFEXOR	C		UNK	14 DAY	
	LEVOTHYROXINE	C		75 ug, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Aug-2012	8732303	EXPEDITED (15-DAY)	Y	OT	US-GLAXOSMITHKLINE-A0989918A	34 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
BLINDNESS	PAXIL	S	ORAL			GLAXOSMITHKLINE
ANXIETY	LEXAPRO	S	UNKNOWN			
VERTIGO	ALPRAZOLAM	S	ORAL			GLAXOSMITHKLINE
DIZZINESS	SERTRALINE HYDROCHLORIDE	S	ORAL	50MG Per day	3 WEEK	
PALPITATIONS	ZOLOFT	S	ORAL	50MG Per day		
ABASIA						
CARDIAC DISORDER						
WITHDRAWAL SYNDROME						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Aug-2012	8734304	EXPEDITED (15-DAY)	N	HO,CA	US-FRI-1000037934	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CONGENITAL CARDIOVASCULAR ANOMALY	LEXAPRO	S	TRANSPLACENTAL			
FAILURE TO THRIVE						
PREMATURE BABY						
RESPIRATORY SYNCYTIAL VIRUS INFECTION						
UNDERWEIGHT						
VOMITING						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Aug-2012	8734576	EXPEDITED (15-DAY)	N	CA	US-FRI-1000037912	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CLEFT PALATE	LEXAPRO	S	TRANSPLACENTAL			
ATRIAL SEPTAL DEFECT						
CONGENITAL ANOMALY						
LUNG DISORDER						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Aug-2012	8734664	EXPEDITED (15-DAY)	N	HO	US-PURDUE-USA-2012-0091484		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC DISORDER	OXYCONTIN	S	ORAL	80 mg, UNK		PURDUE
PAIN	LEXAPRO	S				
ABDOMINAL PAIN UPPER	ALPRAZOLAM	S				
NAUSEA	ROXICODONE	S				
HEADACHE	UNSPECIFIED INGREDIENT	S				
INADEQUATE ANALGESIA						
SOMNOLENCE						
UNEVALUABLE EVENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Aug-2012	8612466	EXPEDITED (15-DAY)	Y	DE,HO	NL-FRI-1000031250	53 YR	Male	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
SUDDEN DEATH	LEXAPRO	S	ORAL	20 mg		
CIRCULATORY COLLAPSE	OMEPRAZOLE	C	ORAL	40 mg		
	ZOCOR	C	ORAL	40 mg		
	LEPONEX	C	ORAL	50 mg		
	LEPONEX	C	ORAL			
	OXAZEPAM	C	ORAL			
	ASCAL	C		100 mg		
	SLOW-K	C	ORAL			
	VITAMIN B-COMPLEX	C				
	ASPIRIN\DIPYRIDAMOLE	C		25/200 mg		
	RAMIPRIL	C	ORAL			
	ASCAL CARDIO BRISPER EFFERVESCENT	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Aug-2012	8735653	EXPEDITED (15-DAY)	Y	HO,OT	US-JNJFOC-20120805291		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
RHABDOMYOLYSIS	RISPERIDONE	S	UNKNOWN			
AGRANULOCYTOSIS	HALOPERIDOL LACTATE	S	UNKNOWN			
DRUG INTERACTION	FENTANYL	S	TRANSDERMAL			
	ZETIA	S	UNKNOWN			
	TRICOR	S	UNKNOWN			
	LIPITOR	S	UNKNOWN			
	THORAZINE	S	UNKNOWN			
	SEROQUEL	S	UNKNOWN			
	ZYPREXA	S	UNKNOWN			
	GEODON	S	UNKNOWN			
	ABILIFY	S	UNKNOWN			

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	ATIVAN	S	UNKNOWN			
	KLONOPIN	S	UNKNOWN			
	COGENTIN	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	CITALOPRAM	S	UNKNOWN			
	PHENELZINE SULFATE	S	UNKNOWN			
	DEPAKOTE	S	UNKNOWN			
	ARICEPT	S	UNKNOWN			
	COLCHICINE	S	UNKNOWN			
	DAPTOMYCIN	S	UNKNOWN			
	UNASYN	S	UNKNOWN			
	ZIAGEN	S	UNKNOWN			
	VALCYTE	S	UNKNOWN			
	CLOFARABINE	S	UNKNOWN			
	CYCLOPHOSPHAMIDE	S	UNKNOWN			
	PREDNISONE	S	UNKNOWN			
	PROGRAF	S	UNKNOWN			
	ALDESLEUKIN	S	UNKNOWN			
	SIROLIMUS	S	UNKNOWN			
	ASPIRIN	S	UNKNOWN			
	CRESTOR	S	UNKNOWN			
	HYDROCHLOROTHIAZIDE	S	UNKNOWN			
	PENICILLIN	S	UNKNOWN			
	ZOSYN	S	UNKNOWN			
	KEFLEX	S	UNKNOWN			
	CEFTRIAXONE	S	UNKNOWN			
	BACTRIM	S	UNKNOWN			
	DILANTIN	S	UNKNOWN			
	NEURONTIN	S	UNKNOWN			
	TEGRETOL	S	UNKNOWN			
	AZATHIOPRINE SODIUM	S	UNKNOWN			

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	SULFASALAZINE	S	UNKNOWN			
	PLAVIX	S	UNKNOWN			
	SIMVASTATIN	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Aug-2012	8750012	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG EFFECT DECREASED	LEXAPRO	S				
PRODUCT SUBSTITUTION ISSUE						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Aug-2012	8750297	DIRECT	N	HO		34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
HOT FLUSH	LEXAPRO	S	ORAL	10 MG ORAL	12 HR	
ANXIETY						
Coordination abnormal						
DISTURBANCE IN ATTENTION						
DIZZINESS						
DYSTONIA						
HEADACHE						
HEART RATE INCREASED						
INCOHERENT						
NAUSEA						
SEROTONIN SYNDROME						
SYNCOPE						
VISUAL IMPAIRMENT						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Aug-2012	8746431	EXPEDITED (15-DAY)	N	OT	2012SP002348	79 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
DRUG INTERACTION	LUNESTA	S	ORAL			
TOXICITY TO VARIOUS AGENTS	LEXAPRO	S				
CRYING	OXYCONTIN	S				
HALLUCINATION, AUDITORY	OXYCONTIN	S				
HALLUCINATION, VISUAL	MORPHINE	S				
SOMNOLENCE	VICODIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Aug-2012	8746685	EXPEDITED (15-DAY)	N	HO	US-PFIZER INC-2012207156		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
CARDIAC DISORDER	ALPRAZOLAM	S				PFIZER
PAIN	ROXICODONE	S				
HEADACHE	LEXAPRO	S				
SOMNOLENCE	OXYCONTIN	S		80 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Aug-2012	8759582	EXPEDITED (15-DAY)		OT	US-FRI-1000038138		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiac disorder	LEXAPRO	S				FOREST
Pain	OXYCONTIN	S		80 mg		
Headache	ALPRAZOLAM	S				
Somnolence	ROXICODONE	S				
	UNSPECIFIED INGREDIENT	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Aug-2012	8762410	NON-EXPEDITED			US-PFIZER INC-2012210339	77 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Neosporin	S		UNK		PFIZER
	LEXAPRO	S		UNK		
	MONOPRIL	S		UNK		
	ZESTORETIC	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Aug-2012	8762503	NON-EXPEDITED			US-PFIZER INC-2012211188	81 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Celebrex	S		UNK		PFIZER
	CODEINE	S		UNK		
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Aug-2012	8760934	EXPEDITED (15-DAY)		HO,OT	US-FRI-1000038136	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO	S				FOREST
Impaired driving ability	LEXAPRO	S				FOREST
Somnolence	TOPAMAX	C				
Feeling abnormal	SOMA	C				
Anger	HYDROCODONE	C				
Crying	DETROL	C				
	PROVIGIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Aug-2012	8761076	EXPEDITED (15-DAY)		DE,CA	US-FRI-1000038192	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypoplastic left heart syndrome	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Aug-2012	8762927	DIRECT		OT		18 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug withdrawal syndrome	LEXAPRO	S	ORAL			
Apathy						
Educational problem						
Homicidal ideation						
Memory impairment						
Mood swings						
Panic attack						
Psychotic disorder						
Shoplifting						
Social problem						
Suicidal ideation						
Theft						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Aug-2012	8762936	DIRECT				42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Urticaria	LEXAPRO	S	ORAL	20 mg once a day po		
Arthralgia						
Cheilitis						
Dyspnoea						
Heart rate irregular						
Insomnia						
Reaction to drug excipients						
Scratch						
Therapy cessation						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Aug-2012	8764255	EXPEDITED (15-DAY)		OT	VE-FRI-1000038254	25 YR	Female	VEN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Scleroderma	LEXAPRO	S	ORAL	2 mg		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Aug-2012	8764454	EXPEDITED (15-DAY)		DE,CA	US-FRI-1000027276		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Spina bifida	LEXAPRO	S	TRANSPLACENTAL	20 mg		FOREST
	LEXAPRO	S				FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Aug-2012	8780050	DIRECT	Y			14 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	LEXAPRO	S				
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Sep-2012	8771147	EXPEDITED (15-DAY)		OT	JP-FRI-1000038347	72 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	LEXAPRO	S	ORAL	10 mg		FOREST
	SERMION	C	ORAL	15 mg		
	DEPAS	C	ORAL	0.5 mg		
	DEPAS	C	ORAL	1 mg		
	ETISEDAN	C	ORAL	1 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Sep-2012	8771155	EXPEDITED (15-DAY)		LT	JP-FRI-1000038270	33 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug-induced liver injury	LEXAPRO	S	ORAL	10 mg		FOREST
Off label use	LEXOTAN	C	ORAL	4 mg		
	REBAMIPIDE	C	ORAL	300 mg		
	URSO	C	ORAL	300 mg		
	TAPIZOL	C	ORAL	30 mg		
	MEDETAX	C	ORAL			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Sep-2012	8717455	EXPEDITED (15-DAY)		LT	JP-FRI-1000037712	63 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Activation syndrome	LEXAPRO	S	ORAL	10 mg		FOREST
Delusion	LEXAPRO	S	ORAL	20 mg		FOREST
Hallucination	LEXAPRO	S	ORAL	10 mg		FOREST
	REMERON	S	ORAL	45 mg		
	ZYPREXA	C	ORAL	2.5 mg		
	ZYPREXA	C	ORAL	5 mg		
	ZYPREXA	C	ORAL	7.5 mg		
	ZYPREXA	C	ORAL	10 mg		
	MEILAX	C	ORAL	2 mg		
	SOLANAX	C	ORAL	0.4 mg		
	AMLODIN OD	C	ORAL	5 mg		
	GLYCYRON	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Sep-2012	8784686	DIRECT		OT		61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anger	LEXAPRO	S				
Anger						
Product substitution issue						
Sleep disorder						
Sleep terror						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Sep-2012	8773336	EXPEDITED (15-DAY)		DE	AU-FRI-1000038423	34 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	LEXAPRO	S	ORAL			FOREST
	LEXAPRO	S	ORAL	OVERDOSE: Unknown dose		FOREST
	OLANZAPINE	C				
	OLANZAPINE	C				
	OXAZEPAM	C				
	OXAZEPAM	C				
	TEMAZEPAM	C				
	TEMAZEPAM	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2012	7878648	EXPEDITED (15-DAY)		HO	US-ASTRAZENECA-2011SE11145	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Back disorder	SYMBICORT PMDI	S	INHALATION	UNKNOWN		
Gait disturbance	NEXIUM	S	ORAL			
Sensation of foreign body	CRESTOR	S	ORAL			
Malaise	LEXAPRO	S	UNKNOWN			
Vomiting	LEXAPRO	S	UNKNOWN	GENERIC		
Hypoaesthesia	PRISTIQ	C				
Hypoaesthesia	ACTINEL	C				
Muscle spasms	OSTEOFORTE	C				
Arthralgia						
Crying						
Drug dose omission						
Dysphonia						
Dyspnoea						
Gastrooesophageal reflux disease						
Incontinence						
Malaise						
Nausea						
Nervousness						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2012	8789606	DIRECT	Y			53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Paraesthesia	DOXYCYCLINE	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Sep-2012	8770943	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2012212509	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Panic disorder	Pristiq	S		UNK		PFIZER
Palpitations	Pristiq	S		50 mg, 1x/day		PFIZER
Nervousness	Effexor	S		UNK		PFIZER
Weight increased	VIIBRYD	S	ORAL	10 mg, 1x/day		
Weight decreased	VIIBRYD	S	ORAL	20 mg, 1x/day		
Hyperhidrosis	CITALOPRAM	S		20 mg, 1x/day		
Abnormal dreams	LEXAPRO	S		UNK		
Insomnia	CELEXA	C		UNK		
Nausea	WELLBUTRIN	C		UNK		
Asthenia	ABILIFY	C		UNK		
Diarrhoea	LEVOTHYROXINE SODIUM	C		75 ug, 1x/day		
Parosmia	GLUCOSAMINE	C		UNK		
Retching	CHONDROITIN	C		UNK		
Drug ineffective	FISH OIL	C		UNK		
	BABY ASPIRIN	C		UNK, as needed		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Sep-2012	8784319	EXPEDITED (15-DAY)		OT	JP-FRI-1000025531	25 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Altered state of consciousness	LEXAPRO	S	ORAL	10 mg		FOREST
Convulsion						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Sep-2012	8791346	DIRECT		LT,OT		89 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abnormal behaviour	LEXAPRO	S	ORAL	from May 1st to May 8th 1st time from June 8th to June 30		TEVA
Suicidal ideation	NAMENDA	C				
Nausea	ARICEPT	C				
Malaise	AXONA MEDICAL FOOD	C				
Confusional state						
Depression						
Imprisonment						
Lethargy						
Physical assault						
Weight decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Sep-2012	8709886	EXPEDITED (15-DAY)		OT	JP-FRI-1000037584	18 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Intentional self-injury	LEXAPRO	S	ORAL	20 mg		FOREST
	CYMBALTA	C	ORAL	40 mg		
Wound	LENDORMIN D	C	ORAL	0.25 mg		
	EVAMYL	C	ORAL	1 mg		
	ABILIFY	C	ORAL	2 mg		
	HALCION	C	ORAL			
	SOMELIN	C	ORAL			
	SOLANAX	C	ORAL			
	DEPAS	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Sep-2012	8712210	EXPEDITED (15-DAY)		OT	JP-FRI-1000037588	19 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Intentional self-injury	LEXAPRO	S	ORAL	10 mg		FOREST
	WYPAX	C	ORAL	0.5 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Sep-2012	8796173	EXPEDITED (15-DAY)		HO	US-BRISTOL-MYERS SQUIBB COMPANY-16946972	70 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Knee arthroplasty	ABILIFY	S		20mg Abilify tab in half. Currently on 10 mg once daily(by breaking half tab)		
Pain	LEXAPRO	S				
Fatigue						
Feeling abnormal						
Wrong technique in drug usage process						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Sep-2012	8799481	NON-EXPEDITED			US-PFIZER INC-2012230063	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	Effexor	S		UNK		PFIZER
Adverse drug reaction	Trazodone HCl	S		UNK		
	PAXIL	S		UNK		
	CELEXA	S		UNK		
	LEXAPRO	S		UNK		
	PROZAC	S		UNK		
	WELLBUTRIN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Sep-2012	7916136	NON-EXPEDITED			US-PFIZER INC-2011089062	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	Pristiq	S	ORAL	50 mg, 1x/day		PFIZER
Malaise	Pristiq	S		UNK		PFIZER
Gastrooesophageal reflux disease	Zoloft	S	ORAL	UNK		PFIZER
Energy increased	ALPRAZOLAM	S				PFIZER
Insomnia	LEXAPRO	S		UNK		
Fatigue	RESTORIL	S		UNK		
Somnolence	SUBOXONE	S				
Choking sensation	PRILOSEC	C		20 (units unspecified), QD		
Abdominal pain upper	VALIUM	C		10 mg, 3x/day		
Flatulence	TRAZODONE	C		50 mg, HS (at bedtime)		
Anxiety	XANAX	C		UNK		
Drug interaction						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Sep-2012	8801187	NON-EXPEDITED			US-009507513-1209USA 005724		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	SAPHRIS	S	ORAL			MERCK
Weight increased	FANAPT	S	ORAL	8 mg, bid		
Abnormal behaviour	LEXAPRO	S				
	SEROQUEL	S				
	risperidone	S				
	PRISTIQ	C				
	EFFEXOR XR	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Sep-2012	8808703	DIRECT	Y	OT			Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sexual dysfunction	LEXAPRO	S	ORAL	Lexapro 5mg once daily oral	1 WK	
	LIPITOR	C				
	VICTOZA	C				
	METFORMIN	C				
	ATENOLOL	C				
	NORVASC	C				
	ASA	C				
	TEMAZEPAM	C				
	XOLATAN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Sep-2012	8802930	EXPEDITED (15-DAY)		CA	US-FRI-1000038751	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Coarctation of the aorta	LEXAPRO	S	TRANSPLACENTAL			FOREST
Atrial septal defect						
Congenital anomaly						
Patent ductus arteriosus						
Ventricular septal defect						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Sep-2012	8783090	NON-EXPEDITED			US-ASTRAZENECA-2012SE70499	38 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	LEXAPRO	S	ORAL			
Confusional state	LEXAPRO	S	ORAL	GENERIC, DAILY		
Insomnia	METOPROLOL SUCCINATE	S	ORAL			
Restlessness	SEROQUEL	S	ORAL			
Memory impairment	SEROQUEL	S	ORAL			
Nasal congestion	SEROQUEL	S	ORAL			
Memory impairment	SEROQUEL	S	ORAL			
Adverse event	SEROQUEL	S	ORAL	GENERIC, DAILY		
Drug ineffective	SEROQUEL	S	ORAL	GENERIC, DAILY		
	FENOFIBRATE	C	ORAL			
	PSYCHOTROPIC MED	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Sep-2012	8809793	EXPEDITED (15-DAY)		HO,OT	US-FRI-1000038823		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	LEXAPRO	S				FOREST
Weight decreased	LEXAPRO	S				FOREST
Injection site erythema	REBIF	S	SUBCUTANEOUS			
Off label use	ALCOHOL	S				
	ACETAMINOPHEN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Sep-2012	8810323	NON-EXPEDITED			US-009507513-1209USA 008841		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	COZAAR	S	ORAL			MERCK
Back pain	AMLODIPINE	S				
Pain in extremity	VENLAFAXINE HYDROCHLORIDE	S				
Abdominal pain upper	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Sep-2012	8470559	EXPEDITED (15-DAY)		OT	JP-FRI-1000029225	42 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	LEXAPRO	S	ORAL	10 mg		FOREST
Facial spasm	LEXAPRO	S	ORAL	20 mg		FOREST
Nausea	FLUVOXAMINE MALEATE	C	ORAL	150 mg		
	EVAMYL	C	ORAL	2 mg		
Vomiting	BROTIZOLAM	C	ORAL	0.25 mg		
Musculoskeletal stiffness	ESTAZOLAM	C	ORAL	2 mg		
Tremor	HORIZON	C	ORAL	15 mg		
Fear	RILYFTER	C	ORAL	10 mg		
Dystonia						
Excessive eye blinking						
Tardive dyskinesia						
Tremor						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Sep-2012	8738226	NON-EXPEDITED			US-PFIZER INC-2012205320		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nervousness	Pristiq	S	ORAL	50 mg, 1x/day		PFIZER
	LEXAPRO	S		20 mg, UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Sep-2012	8774328	NON-EXPEDITED			US-PFIZER INC-2012215878	43 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	EFFEXOR	S		UNK		PFIZER
	Neurontin	S	ORAL	600 mg, 3x/day		PFIZER
	AMOXICILLIN	S		UNK		PFIZER
	IBUPROFEN	S		UNK		PFIZER
	PHENYTOIN	S		UNK		PFIZER
	FEXOFENADINE HYDROCHLORIDE	S		UNK		
	FLURBIPROFEN	S		UNK		PFIZER
	KETOPROFEN	S		UNK		PFIZER
	KETOROLAC TROMETHAMINE	S		UNK		PFIZER
	Lodine	S		UNK		PFIZER
	MECLOFENAMATE SODIUM	S		UNK		PFIZER
	Meclomen	S		UNK		
	MEFENAMIC ACID	S		UNK		PFIZER
	METHOCARBAMOL	S		UNK		PFIZER
	Momentum	S		UNK		PFIZER
	MOTRIN	S		UNK		
	NABUMETONE	S		UNK		PFIZER
	NAPROXEN SODIUM	S		UNK		PFIZER
	Omnicef	S		UNK		PFIZER
	Ponstel	S		UNK		PFIZER
	PRAVASTATIN SODIUM	S		UNK		
	Effexor XR	S		UNK		PFIZER
	VALERIAN ROOT	S		UNK		UNKNOWN
	Advil	S		UNK		PFIZER
	Anacin	S		UNK		PFIZER
	Ansaid	S		UNK		PFIZER

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	Celebrex	S		UNK		PFIZER
	DICLOFENAC	S		UNK		PFIZER
	Dimetapp Sinus	S		UNK		PFIZER
	CEFADROXIL	S		UNK		
	Dristan	S		UNK		PFIZER
	Daypro	S		UNK		PFIZER
	CECLOR	S		UNK		
	KEFLEX	S		UNK		
	ASPIRIN	S		UNK		
	LEXAPRO	S		UNK		
	AUGMENTIN	S		UNK		
	QUINIDINE	S		UNK		
	PRAVACHOL	S		UNK		
	TIZANIDINE	S		UNK		
	ZANAFLEX	S		UNK		
	CYMBALTA	S		UNK		
	ALLEGRA	S		UNK		
	MAXZIDE	C		UNK		
	ACULAR	S		UNK		
	ALEVE	S		UNK		
	ALKA SELTZER	S		UNK		
	ANAPROX	S		UNK		
	ASCRIPTIN	S		UNK		
	ASPIRIN "BAYER"	S		UNK		
	BUFFERIN	S		UNK		
	CAMA	S		UNK		
	CATAFLAM	S		UNK		
	CEFACLOR	S		UNK		
	CEPHALEXIN	S		UNK		
	FELDINE	S		UNK		
	FENOPROFEN	S		UNK		

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	FIORINAL	S		UNK		
	HALTRAN	S		UNK		
	IBUPRIN	S		UNK		
	INDOCIN	S		UNK		
	INDOMETHACIN	S		UNK		
	MEDIPREN	S		UNK		
	MOXATAG	S		UNK		
	NALFON	S		UNK		
	NAPRELAN	S		UNK		
	NAPROSYN	S		UNK		
	NAPROXEN	S		UNK		
	NORFLEX	S		UNK		
	NORGESIC	S		UNK		
	NUPRIN	S		UNK		
	OCUFEN	S		UNK		
	ORPHENADRINE	S		UNK		
	ORUDIS	S		UNK		
	ORUVAIL	S		UNK		
	PAMPRIN	S		UNK		
	PEPTO-BISMOL	S		UNK		
	PERCODAN	S		UNK		
	PRINCIPEN	S		UNK		
	PROFENAL	S		UNK		
	PROPOXYPHENE	S		UNK		
	EQUAGESIC	S		UNK		
	ECOTRIN	S		UNK		
	EMPIRIN	S		UNK		
	CLINORIL	S		UNK		
	CEFTIN	S		UNK		
	AGGRENOX	S		UNK		
	COMBUNOX	S		UNK		

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	CONGESPIRIN	S		UNK		
	DARVON	S		UNK		
	DULOXETINE	S		UNK		
	NEXIUM	C		UNK		
	VENTOLIN	C		UNK		
	LORATADINE	C		UNK		
	MAXALT	C		UNK		
	TRAZODONE	C		UNK		
	OMEPRAZOLE	C		UNK		
	ADVAIR	C		UNK		
	FLUOXETINE	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Sep-2012	8814085	NON-EXPEDITED			US-PFIZER INC-2012237511	53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	AMLODIPINE BESILATE	S		UNK		PFIZER
Myalgia	VENLAFAXINE HYDROCHLORIDE	S		UNK		PFIZER
Pain in extremity	LOSARTAN	S		UNK		
Abdominal pain upper	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Sep-2012	8814860	EXPEDITED (15-DAY)		DE,CA	US-FRI-1000038907	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ebstein's anomaly	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Sep-2012	8815086	EXPEDITED (15-DAY)		CA	US-FRI-1000038912	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fallot's tetralogy	LEXAPRO	S	TRANSPLACENTAL			FOREST
Atrial septal defect						
Congenital anomaly						
Pulmonary artery stenosis congenital						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Oct-2012	8819819	EXPEDITED (15-DAY)		CA	US-FRI-1000039038	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrial septal defect	LEXAPRO	S	TRANSPLACENTAL			FOREST
Cleft palate						
Congenital anomaly						
Diaphragmatic hernia						
Talipes						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Oct-2012	8821152	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16492332	47 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Heart rate increased	BUSPAR	S				BRISTOL MYERS SQUIBB
Insomnia	LEXAPRO	S	ORAL	5mg(27Jun-2011),2.5mg 2 times a day,15mg, 10mg,Dosingtime changed from bedtime morning on Mar 2012		
Nervousness	LEXAPRO	S	ORAL	5mg(27Jun-2011),2.5mg 2 times a day,15mg, 10mg,Dosingtime changed from bedtime morning on Mar 2012		
	PRILOSEC	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Oct-2012	8823411	EXPEDITED (15-DAY)		CA	US-FRI-1000039085		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Talipes	LEXAPRO	S	TRANSPLACENTAL			FOREST
Hypospadias						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Oct-2012	9227449	NON-EXPEDITED		OT	PHEH2011US02520	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hormone level abnormal	CLIMARA (ESTRADIOL)	S				
Vaginal haemorrhage	LEXAPRO (ESCITALOPRAM OXALATE)	S				
Application site irritation	DIAZEPINE (NO INGREDIENTS/ SUBSTANCES)	C				
Drug ineffective	AMLODIPINE (AMLODIPINE)	C				
Application site burn						
Pain in extremity						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Oct-2012	8771201	EXPEDITED (15-DAY)		DE,HO,OT	US-BRISTOL-MYERS SQUIBB COMPANY-16879645	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pneumonia aspiration	ABILIFY	S	ORAL	started either 2 or 5mg,dose increased to 10mg,Jul12		
Dysphagia	BUSPAR	S				BRISTOL MYERS SQUIBB
Parkinsonism	LEXAPRO	S				
Fall	LEXAPRO	S				
Clavicle fracture	AMBIEN	S		QHS		
	LIPITOR	C				
	ALLEGRA	C				
	VITAMIN C	C				
	VITAMIN D3	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Oct-2012	8823107	EXPEDITED (15-DAY)		CA	US-FRI-1000039056		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pulmonary artery stenosis congenital	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Oct-2012	8772502	EXPEDITED (15-DAY)		OT	AU-FRI-1000038315	< 1 DAY	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Neonatal respiratory distress syndrome	LEXAPRO	S	TRANSPLACENTAL			FOREST
Drug withdrawal syndrome	ARIPIPRAZOLE	S	TRANSPLACENTAL	10 mg		
Foetal exposure during pregnancy	BREAST FEEDING SUPPORT	C	ORAL			
	FEFOL	C	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Oct-2012	8827698	NON-EXPEDITED			US-PFIZER INC-2012244846		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	Celebrex	S		UNK		PFIZER
Dizziness	LEXAPRO	S		UNK		
Drug interaction						
Headache						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Oct-2012	8832534	DIRECT	Y	OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depression	LEXAPRO	S	ORAL			
Anxiety						
Insomnia						
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Oct-2012	8837262	DIRECT	Y	OT		57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal discomfort	CELEXA	S	ORAL	Celexa 20 daily PO - liquid		
Abdominal distension						
Diarrhoea						
Headache						
Hypersensitivity						
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	8838284	EXPEDITED (15-DAY)		CA	US-FRI-1000039299	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Congenital diaphragmatic hernia	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						
Neonatal respiratory distress syndrome						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	8838448	EXPEDITED (15-DAY)		CA	US-FRI-1000039305		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Aortic stenosis	LEXAPRO	S	TRANSPLACENTAL			FOREST
Atrial septal defect						
Congenital anomaly						
Patent ductus arteriosus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227139	NON-EXPEDITED	Y	OT,RI	1000029076	53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Angioedema	LEXAPRO (ESCITALOPRAM OXALATE) (10 MILLIGRAM, TABLETS)	S	ORAL	10 mg (10mg, 1 in 1 D), Oral		
	AMLODIPINE (AMLODIPINE) (AMLODIPINE)	C				
	ZOLPIDEM (ZOLPIDEM) (ZOLPIDEM)	C				
	HYZAAR (HYZAAR) (HYZAAR)	C				
	PREMARIN (ESTROGEN CONJUGATED) (ESTROGENS CONJUGATED)	C				
	TOPROL (METOPROLOL SUCCINATE) (METOPROLOL SUCCINATE)	C				
	TRAZODONE (TRAZODONE) (TRAZODONE)	C				
	MAXALT (RIZATRIPTAN) (RIZATRIPTAN)	C				
Rash						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227154	NON-EXPEDITED		HO	1000029116	21 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO (ESCITALOPRAM OXALATE)	S	ORAL			
Crying	LOESTRIN FE (NORETHINDRONE, ETHINYL ESTRADIOL) (NORETHINDRONE, ETHINYL ESTRADIOL)	C				
Anger						
Social avoidant behaviour						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227158	NON-EXPEDITED		OT,RI	1000029147		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicide attempt	LEXAPRO	S	ORAL			
Depression						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227160	NON-EXPEDITED		OT,RI	1000029221	30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
Depression						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227164	NON-EXPEDITED		OT,RI	1000029263	40 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO	S				
Hyperhidrosis	WELLBURTIN (BUPROPION HYDROCHLORIDE) (BUPROPION HYDROCHLORIDE)	C				
Blood testosterone decreased						
Feeling cold						
Irritability						
Libido decreased						
Tremor						
Weight increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227177	NON-EXPEDITED	Y		1000029279	49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Self-injurious ideation	LEXAPRO	S	ORAL			
	MARIJUANA (CANNABIS SATIVA) (CANNABIS SATIVA)	C				
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227187	NON-EXPEDITED		OT,RI	1000029340	35 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO (ESCITALOPRAM OXALATE) (20 MILLIGRAM, TABLETS)	S	ORAL			
Anger	XANAX (ALPRAZOLAM) (ALPRAZOLAM)	C				
Agitation						
Crying						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227209	NON-EXPEDITED			1000029628	78 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	LEXAPRO	S	ORAL			
	SPIRIVA (TIOTROPIUM BROMIDE) (TIOTROPIUM BROMIDE)	C				
	HYDROCHLOROTHIAZIDE (HYDROCHLOROTHIAZIDE) (HYDROCHLOROTHIAZIDE)	C				
	SYNTHROID (LEVOTHYROXINE SODIUM)(LEVOTHYROXINE SODIUM)	C				
	CRESTOR (ROSUVASTATIN CALCIUM)(ROSUVASTATIN CALCIUM)	C				
	BONIVA (IBANDRONATE SODIUM) (IBANDRONATE SODIUM)	C				
	DEXLANSOPRAZOLE (DEXLANSOPRAZOLE) (DEXLANSOPRAZOLE)	C				
	ALBUTEROL (ALBUTEROL) (ALBUTEROL)	C				
	SYMBICORT (BUDESONIDE, FORMOTEROL)(BUDESONIDE, FORMOTEROL)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227213	NON-EXPEDITED	Y	OT,RI	1000029980	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	LEXAPRO (ESCITALOPRAM OXALATE)	S				
Ventricular arrhythmia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227332	NON-EXPEDITED		HO	1000025159	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicide attempt	LEXAPRO (ESCITALOPRAM OXALATE) (20 MILLIGRAM, TABLETS)	S	ORAL	20mg (20mg, 1 in 1 D), Oral		
Irritability	DEPAKOTE (VALPROATE SEMISODIUM)	C				
Crying	KLONOPIN (CLONAZEPAM) (TABLETS)	C				
	UNSPECIFIED MEDICATIONS NOS (UNSPECIFIED MEDICATIONS NOS)	S				
Depression						
Paraesthesia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227340	NON-EXPEDITED		HO	1000025511	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ataxia	LEXAPRO (ESCITALOPRAM OXALATE) 20 MILLIGRAM, TABLEETS)	S	ORAL	20mg (20mg, 1 in 1 D), Oral		
Hallucination						
Insomnia						
Panic attack						
Vertigo						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227349	NON-EXPEDITED	Y	OT,RI	1000026745	49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diabetes mellitus	LEXAPRO	S	ORAL	5 mg (5mg, 1 in 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227359	NON-EXPEDITED		HO	1000026846	26 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicide attempt	LEXAPRO	S	ORAL	10mg (10mg, 1 in 1 D), Oral		
	KEPPRA (LEVETIRACETAM)	C				
	ZONEGRAN (ZONISAMIDE)	C				
	VIMPAT (LACOSAMIDE)	C				
	LORAZEPAM (LORAZEPAM)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227376	NON-EXPEDITED	Y	OT,RI	1000027216		Male	DNK

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO (ESCITALOPRAM OXALATE)	S	ORAL			
	ANTI-EPILEPTIC DRUGS (ANTI-EPILEPTIC DRUGS) (ANTI-EPILEPTIC DRUGS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227386	NON-EXPEDITED		OT,RI	1000027292		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	LEXAPRO (ESCITALOPRAM OXALATE)	S		5 gm, 1 in 1 D		
Headache	ARMOUR (THYROID (THYROID)	C				
Feeling abnormal	ATIVAN (LORAZEPAM) (LORAZEPAM)	C				
	XANAX (ALPRAZOLAM) (ALPRAZOLAM)	C				
	CATAPRES (CLONIDINE) (CLONIDINE)	C				
Burning sensation						
Cold sweat						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227395	NON-EXPEDITED		DE	1000027438	49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Completed suicide	LEXAPRO	S				
	TOPROL XL (METOPROLOL) (METOPROLOL)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227404	NON-EXPEDITED	Y	OT,RI	1000028429		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiac flutter	LEXAPRO	S				
Hair colour changes						
Tremor						
Vision blurred						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227413	NON-EXPEDITED		OT,RI	1000028448	84 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO	S	ORAL	(5 mg, 1 in 1 D)		
Insomnia	VITAMIN B 12	C				
Crying						
Diarrhoea						
Feeling abnormal						
Neck pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227420	NON-EXPEDITED		OT,RI	1000028865		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mania	LEXAPRO	S		1 in 1 D		
Depression						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227611	NON-EXPEDITED		HO	1000030362	90 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anaemia	LEXAPRO	S				FOREST
Contusion	ASPIRIN (ACETYLSALICYLIC ACID)	C				
Fatigue	WARFARIN (WARFARIN)	C				
	DIAZEPAM (DIAZEPAM)	S				
Dizziness						
Fall						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227633	NON-EXPEDITED		OT,RI	1000030561	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	LEXAPRO	S		1 in 1 D		
Malaise	LIPITOR (ATORVASTATIN CALCIUM) (ATORVASTATIN CALCIUM)	C				
Abdominal discomfort						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227638	NON-EXPEDITED		OT,RI	100030625	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Platelet count decreased	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227646	NON-EXPEDITED		OT,RI	1000030827	48 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypersensitivity	LEXAPRO	S				
	NITROSTAT(NITROGLYCERIN) (NITROGLYCERIN)	C				
	ASPIRIN (ACETYLSALICYLIC ACID) (ACETYLSALICYLIC ACID)	C				
	QUINAPRIL (QUINAPRIL) (QUINAPRIL)	C				
	PLAVIX (CLOPIDOGREL BISULFATE) (CLOPIDOGREL BISULFATE)	C				
	XANAX (ALPRAZOLAM) (ALPRAZOLAM)	C				
	COREG (CARVEDILOL) (CARVEDILOL)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227654	NON-EXPEDITED		OT,RI	1000031506	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Heart rate increased	LEXAPRO	S	ORAL	10 mg, 1 in 1 D		
Fatigue						
Palpitations						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227663	NON-EXPEDITED	Y	OT,RI	1000037036		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatic enzyme increased	LEXAPRO	S				FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227672	NON-EXPEDITED		OT,RI	1000037120	31 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO	S	ORAL			
Dizziness						
Hallucination						
Hypoaesthesia						
Nausea						
Tachyphrenia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227674	NON-EXPEDITED	Y	OT,RI	1000036640		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastrointestinal haemorrhage	LEXAPRO	S	ORAL			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227680	NON-EXPEDITED		OT,RI	1000036719	32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO	S	ORAL			
	CLONAZEPAM (CLONAZEPAM) (CLONAZEPAM)	C				
Depression						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227693	NON-EXPEDITED		OT,RI	100023627	78 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO	S	ORAL	20 mg, 1 in 1 D		
	ADVAIR	C				
	METFORMIN	C				
	GLIPIZIDE	C				
	LEVOTHYROXINE	C				
	ZYPREXA	C				
	LORAZEPAM	C				
	DIGOXIN	C				
	TAZTIA	C				
Drug ineffective						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227707	NON-EXPEDITED	Y	OT,RI	1000023652	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227719	NON-EXPEDITED	Y	OT,RI	1000024125	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	LEXAPRO	S	ORAL	10 mg 1 in 1 D		
	VYTORIN	C				
	SYNTHROID	C				
Electrocardiogram QT prolonged						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227726	NON-EXPEDITED	Y	OT,RI	1000024585	29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	LEXAPRO	S	ORAL			
Maternal exposure during pregnancy	ZOFRAN (ONDANSETRON) (ONDANSETRON)	C				
	PRENATAL VITAMIN (PRENATAL VITAMIN) (PRENATAL VITAMIN)	C				
	ZINC (ZINC) (ZINC)	C				
	FISH OIL (FISH OIL) (FISH OIL)	C				
	VITAMIN B-12 (CYANOCOBALAMIN) (CYANOCOBALAMIN)	C				
	VALTREX (VALACICLOVIR HYDROCHLORIDE) (VALACICLOVIR HYDROCHLORIDE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227747	NON-EXPEDITED	Y	OT,RI	1000024939	43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO	S	ORAL			
	LIPOFEN (FENOFIBRATE) (FENOFIBRATE)	C				
	VICODIN (HYDROCODONE, ACETAMINOPHEN) (HYDROCODONE ACETAMINOPHEN)	C				
	VALIUM (DIAZEPAM) (DIAZEPAM)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227757	NON-EXPEDITED		HO	1000025082	15 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO	S	ORAL			
Self-injurious ideation	FOCALIN XR (DEXMETHYLPHENIDATE HYDROCHLORIDE) (DEXMETHYLPHENIDATE HYDROCHLORIDE)	C				
	KLONOPIN (CLONAZEFAM) (CLONAZEPAM)	C				
Off label use						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	9227928	NON-EXPEDITED		OT,RI	1000037681		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Urinary retention	LEXAPRO	S				FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Oct-2012	8839352	EXPEDITED (15-DAY)		OT	BR-JNJFOC-20121004089		Female	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gait disturbance	INVEGA SUSTENNA	S	INTRAMUSCULAR			
Expressive language disorder	INVEGA SUSTENNA	S	INTRAMUSCULAR			
Bradyphrenia	INVEGA SUSTENNA	S	INTRAMUSCULAR			
Muscle rigidity	INVEGA SUSTENNA	S	INTRAMUSCULAR			
Tremor	LEXAPRO	S	UNKNOWN			
Balance disorder	LEXAPRO	S	UNKNOWN			
Malaise						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Oct-2012	8842415	DIRECT		HO,DS,LT,OT,RI		23 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	LEXAPRO	S	ORAL			FOREST
Loss of libido	LEXAPRO	C				
Depression						
Derealisation						
Emotional disorder						
Hearing impaired						
Insomnia						
Restlessness						
Sexual dysfunction						
Suicidal ideation						
Tinnitus						
Visual impairment						
Withdrawal syndrome						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Oct-2012	8774784	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2012220803		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug dependence	Effexor	S		UNK		PFIZER
Malaise	LEXAPRO	S		20 mg, UNK		
Asthenia						
Drug dose omission						
Fatigue						
Feeling abnormal						
Influenza like illness						
Insomnia						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Oct-2012	8821183	EXPEDITED (15-DAY)			IE-FRI-1000039113	34 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Leukopenia	LEXAPRO	S	ORAL	10 mg		FOREST
Neutropenia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Oct-2012	8846544	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-A0997673A	41 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abortion spontaneous	Wellbutrin	S	UNKNOWN			GLAXOSMITHKLINE
Drug ineffective	Celexa	S	UNKNOWN			
Exposure during pregnancy	Prozac	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	No concurrent medications	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Oct-2012	8770792	EXPEDITED (15-DAY)		HO	JP-ASTRAZENECA-2012SE64633	29 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatitis acute	FK949E	S	ORAL			
	LEXAPRO	S	ORAL			
	GASLON N	C				
	KAKKONTOU	C	ORAL			
	KAKKONTOU	C	ORAL			
	CEFAPICOL	C	INTRAVENOUS	1 g		
	ADONA	C	INTRAVENOUS	50 mg		
	LACTEC G	C		500 ml		
	EL-SOLUTION NO. 3	C		500 to 1000 ml		
	BEASLIMIN	C		10 ml		
	GASTER	C		20 mg		
	AMIGRAND	C		500 ml		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Oct-2012	8848801	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2012S1020958	25 YR	Female	ITA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Agitation	ALPRAZOLAM	S	ORAL			MYLAN
Hyperhidrosis	CITALOPRAM HYDROBROMIDE	S				
Withdrawal syndrome	LEXAPRO	S				
Drug interaction						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Oct-2012	8851676	DIRECT		DS		40 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Paraesthesia	LEXAPRO	S				
Brain injury						
Drug dependence						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Oct-2012	9227912	NON-EXPEDITED	Y	OT,RI	1000037193	30 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Priapism	LEXAPRO	S	ORAL	20 MG (20 MG, 1 IN 1 D), ORAL		
	ABILIFY (ARIPIPRAZOLE) (ARIPIPRAZOLE)	C				
	TEGRETAL (CARBAMAZEPINE) (CARBAMAZEPINE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Oct-2012	8498406	EXPEDITED (15-DAY)			JP-FRI-1000029489	39 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Decreased appetite	LEXAPRO	S	ORAL	10 mg		FOREST
Nausea	ALPRAZOLAM	C	ORAL	1.2 mg		
Diarrhoea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Oct-2012	8859453	EXPEDITED (15-DAY)		OT	DSA_60271_2012		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abortion spontaneous	WELLBUTRIN	S				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Oct-2012	8857679	NON-EXPEDITED			US-PFIZER INC-2012263615		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Weight increased	Effexor	S		UNK		PFIZER
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Oct-2012	8877503	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2012228813		Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pharyngeal oedema	Efexor XR	S		UNK		PFIZER
Alopecia	LEXAPRO	S		UNK		
	CIPRAMIL	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Oct-2012	9228387	NON-EXPEDITED		OT	DSA_56025_2012		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	WELLBUTRIN	S				
Drug ineffective						
Product quality issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Oct-2012	9178207	EXPEDITED (15-DAY)		OT	US-RB-045963-12	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Foetal exposure during pregnancy	Subutex	S	TRANSPLACENTAL			RECKITT BENCKISER
Premature baby	PRENATAL VITAMINS	S	TRANSPLACENTAL	Dosing details unknown		
Low birth weight baby	Lexapro	S	TRANSPLACENTAL	Before bed time		
Tremor neonatal	Nicotine	S	TRANSPLACENTAL	Dosing details unknown		
Dacryostenosis congenital						
Gastrooesophageal reflux disease						
Rash neonatal						
Restlessness						
Vomiting neonatal						
Weight decrease neonatal						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Oct-2012	8870308	DIRECT	Y			42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Product substitution issue	LEXAPRO	S	ORAL			
Drug effect decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Oct-2012	9179706	EXPEDITED (15-DAY)		OT	US-FRI-1000039700	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nephrolithiasis	LEXAPRO	S	ORAL	20 mg		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Oct-2012	8879769	EXPEDITED (15-DAY)		CA	US-FRI-1000039883	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Congenital aortic anomaly	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Nov-2012	8889330	DIRECT	Y	LT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Bipolar I disorder	LEXAPRO	S	ORAL	20 mg one daily oral	3 WK	
Disease recurrence						
Suicidal ideation						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Nov-2012	8891356	DIRECT	Y			42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug effect decreased	LEXAPRO	S	ORAL	20 mg QD PO		
Product substitution issue						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Nov-2012	8824908	EXPEDITED (15-DAY)		HO	JP-009507513-1208JPN 006967	49 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dizziness	PEGINTRON	S	SUBCUTANEOUS	1.3 Microgram per kilogram, qw		MERCK
Asthenia	PEGINTRON	S	SUBCUTANEOUS	1.5 Microgram per kilogram, UNK		MERCK
	PEGINTRON	S	SUBCUTANEOUS	1.5 Microgram per kilogram, qw		MERCK
	PEGINTRON	S	SUBCUTANEOUS	40 Microgram per kilogram, qw		MERCK
	PEGINTRON	S	SUBCUTANEOUS	60 Microgram per kilogram, qw		MERCK
	PEGINTRON	S	SUBCUTANEOUS	80 Microgram per kilogram, qw		MERCK
	REBETOL	S	ORAL	800 mg, qd		MERCK
	REBETOL	S	ORAL	400 mg, qd		MERCK
	REBETOL	S	ORAL	800 mg, qd		MERCK
	TELAVIC	S	ORAL	2250 mg, qd		
	TELAVIC	S	ORAL	1500 mg, qd		
	LEXAPRO	S	ORAL	10 mg, qd		
	DESYREL	S	ORAL	50 mg, qd		
	MUCOSTA	C	ORAL	300 mg, qd		
	LOXONIN	C	ORAL	UNK UNK, prn		
	APHTASOLON	C	PARENTERAL	UNK UNK, prn		
	HACHIAZULE GARGLE	C	PARENTERAL	UNK, prn		
	NAUZELIN	C	ORAL	3 DF, qd		
	NAUZELIN	C				
	LAC-B	C	ORAL	3 g, qd		
	PRIMPERAN	C	INTRAVENOUS	1 mg, qd		
	VITAMEDIN	C	ORAL	3 DF, qd		
	PURSENNID (sennosides)	C	ORAL	UNK, prn		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Nov-2012	8895770	EXPEDITED (15-DAY)		HO,CA,OT	US-JNJFOC-20121101479		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cleft lip and palate	TOPAMAX	S	TRANSPLACENTAL			
Ear infection	LEXAPRO	S	TRANSPLACENTAL			
	TRAMADOL	S	TRANSPLACENTAL			
	VALACYCLOVIR	S	TRANSPLACENTAL			
	PRENATAL VITAMINS	C	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Nov-2012	8772506	EXPEDITED (15-DAY)		LT	AU-FRI-1000038314		Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gestational diabetes	LEXAPRO	S				FOREST
Hyperemesis gravidarum	ARIPIPRAZOLE	S		10 mg		
Pregnancy						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Nov-2012	8819171	NON-EXPEDITED			US-PFIZER INC-2012241891	79 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	Xanax	S	ORAL	0.5 mg, as needed		PFIZER
Memory impairment	Benicar	S	ORAL	20 mg, daily		
Blood glucose increased	LEXAPRO	S	ORAL	5 mg, daily		
	ALPRAZOLAM	S	ORAL	0.5 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Nov-2012	8906374	DIRECT	Y			32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Product substitution issue	LEXAPRO	S	ORAL			
Anxiety						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Nov-2012	8903932	NON-EXPEDITED			US-ASTRAZENECA-2012SE82545	45 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Injury	SEROQUEL	S	ORAL			ZENECA
Off label use	LEXAPRO	S	UNKNOWN			
Adverse reaction						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Nov-2012	8905499	NON-EXPEDITED			US-BAYER-2012-114386		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Unevaluable event	BEYAZ	S		UNK		BAYER
Drug interaction	LEXAPRO	S				
	UNSPECIFIED INGREDIENT	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Nov-2012	8905692	EXPEDITED (15-DAY)		HO	US-FRI-1000040353	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VIth nerve paralysis	LEXAPRO	S	ORAL	10 mg		FOREST
	LUAF41156	S	ORAL	0.5 mg		
	CLARITIN	C				
	FLONASE	C				
	LISINOPRIL	C				

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15-Nov-2012	8346249	EXPEDITED (15-DAY)		OT	US-JNJFOC-20120106642		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abortion spontaneous	TOPAMAX	S	ORAL			
Exposure during pregnancy	CLINDAMYCIN	S	VAGINAL			
	TERBUTALINE	S	ORAL			
	PROMETRIUM	S	ORAL			
	LEXAPRO	S	ORAL			
	LITHIUM CARBONATE	S	ORAL			
	BETAMETHASONE	S	UNKNOWN			
	NIFEDIPINE	S	UNKNOWN			
	ZITHROMAX	S	UNKNOWN			
	ETHINYL ESTRADIOL \ETHYNODIOL DIACETATE	S	ORAL			
	SULFAMETHOXAZOLE \TRIMETHOPRIM	S	ORAL			
	NITROFURANTOIN	S	ORAL			
	CEPHALEXIN	S	ORAL			
	BUSPIRONE	S	ORAL			
	AMPICILLIN	S	UNKNOWN			
	NATELLE	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Nov-2012	8914006	DIRECT		HO,LT		71 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Product substitution issue	LEXAPRO	S	ORAL	20mg 1 in PM po		
Blood pressure increased						
Chest discomfort						
Crying						
Heart rate increased						
Hyperhidrosis						
Hypersensitivity						
Insomnia						
Nausea						
Nightmare						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Nov-2012	8828773	EXPEDITED (15-DAY)		HO	AU-FRI-1000039272	86 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Psychotic disorder	LEXAPRO	S	ORAL	5 mg		FOREST
Joint swelling	LEXAPRO	S		20 mg		FOREST
Dyspnoea	LEXAPRO	S	ORAL	Extra tablets-dose, quantity unknown		
Anxiety	IRBESARTEN	C		300 mg		
Cognitive disorder	IRBESARTEN	C		75 mg		
Confusional state	FUROSEMIDE	C				
Hyponatraemia	GLUCOSAMINE	C				
Tremor	SPIRONOLACTONE	C				
Nausea	MAGNESIUM CARBONATE	C				
Overdose	DABIGATRAN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Nov-2012	8915807	EXPEDITED (15-DAY)		OT	IE-FRI-1000040464		Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood sodium increased	LEXAPRO	S	ORAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Nov-2012	8918540	NON-EXPEDITED			US-ASTRAZENECA-2012SE 18892	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug interaction	NEXIUM	S	ORAL			
Feeling abnormal	LEXAPRO	S	ORAL			
Adverse event	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	VALIUM	C				
	BENTYL	C				
	CORGARD	C				
	ZANTAC	C				
	CARAFATE	C				
	LYRICA	C				
	ELAVIL	C				
	ZOFRAN	C				
	VITAMIN E	C				
	CO Q 10	C				
	VITAMIN B12	C				
	RESTASIS	C				
	CALCIUM	C				
	GLUCOSAMINE	C				
	FISH OIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Nov-2012	8674250	EXPEDITED (15-DAY)		OT	JP-FRI-1000037216	64 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Liver disorder	LEXAPRO	S	ORAL	10 mg		FOREST
	LEXAPRO	S	ORAL	20 mg		FOREST
	LEXAPRO	S	ORAL	10 mg		FOREST
	SELENICA	S	ORAL	400 mg		
	SELENICA	S	ORAL	600 mg		
	ZYPREXA	S	ORAL	5 mg		
	ZYPREXA	S	ORAL	10 mg		
	ZYPREXA	S	ORAL	15 mg		
	ZYPREXA	S	ORAL	10 mg		
	DOGMATYL	C	ORAL	450 mg		
	WINTERMIN	C		30 mg		
	NELBON	C	ORAL	10 mg		
	CELECOX	C	ORAL	200 mg		
	MUCOSTA	C	ORAL	200 mg		
	MAGMITT	C	ORAL			
	FORSENID	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Nov-2012	8920235	EXPEDITED (15-DAY)		CA	US-FRI-1000040534	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ectopic kidney	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Nov-2012	8902906	NON-EXPEDITED			US-PFIZER INC-2012279631	30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	Vistaril	S	ORAL	50 mg, 3x/day as necessary		PFIZER
Weight increased	LEXAPRO	S	ORAL	10 mg, daily		
Arthropathy	LEXAPRO	S	ORAL	20 mg, 1x/day		
Depression	LEXAPRO	S	ORAL	10 mg, 1x/day		
	KLONOPIN	S	ORAL	0.5 mg, 2x/day		
	TOPAMAX	S		25 mg, Daily		
	CYMBALTA	S	ORAL	20 mg, Daily		
	CYMBALTA	S				
	ADIPEX	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Nov-2012	8932478	DIRECT		DS		35 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depression	LEXAPRO	S	ORAL			FOREST
Abnormal dreams						
Impaired work ability						
Mental disorder						
Paraesthesia						
Product formulation issue						
Product quality issue						
Suicidal ideation						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Nov-2012	8927359	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-17142068		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mania	ABILIFY TABS 5 MG	S		5 mg		
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Nov-2012	8928958	EXPEDITED (15-DAY)		OT	CN-FRI-1000040641	16 YR	Male	CHN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO	S	ORAL	5 mg		FOREST
Hypokinesia	LEXAPRO	S	ORAL	10 mg		FOREST
Hypersomnia						
Off label use						
Weight increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Nov-2012	8937996	DIRECT	Y	OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	LEXAPRO	S	ORAL			
Irritability	CELEXA	S				
Mood swings						
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Nov-2012	8942228	DIRECT	Y	HO		64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Serotonin syndrome	WELLBUTRIN SR	S				
	FAMOTADINE	C				
	PROTONIX	C				
	PLAVIX	C				
	FUROSEMIDE	C				
	ISOSORBIDE	C				
	PLETAL	C				
	VYTORIN	C				
	METOPROLAM	C				
	SINGULAIR	C				
	ASPIRIN	C				
Sepsis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Dec-2012	8939078	NON-EXPEDITED			US-PFIZER INC-PRP-00036	40 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	Inderal	S	ORAL	80 mg, 1x/day		PFIZER
Fatigue	Inderal	S				PFIZER
Malaise	LEXAPRO	S	ORAL	10 mg, 1x/day,week 1		
Dizziness	LEXAPRO	S		5 mg, UNK,week 2		
Feeling abnormal	LEXAPRO	S		2.5 mg, UNK,week 3		
Depression						
Dizziness						
Feeling abnormal						
Heart rate abnormal						
Malaise						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Dec-2012	8941294	NON-EXPEDITED			US-BAYER-2012-117104	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sluggishness	Betaseron	S		UNK		BAYER
Fatigue	AMPYRA	S	ORAL	10 mg, BID		
	LEXAPRO	S		UNK		
	PROZAC	S		UNK		
	METOPROLOL	C		50 mg, UNK		
	ASPIRIN	C		UNK		
	FOSAMAX	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Dec-2012	8942473	EXPEDITED (15-DAY)		OT	US-JNJFOC-20121111552		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Imprisonment	RISPERDAL	S	ORAL			
Obsessive-compulsive disorder	RISPERDAL	S	ORAL			
Adverse drug reaction	LEXAPRO	S	ORAL			
	RISPERIDONE	S	ORAL			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Dec-2012	8953308	EXPEDITED (15-DAY)		OT	US-JNJFOC-20121112054		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Extrapyramidal disorder	RISPERIDONE	S	UNKNOWN			
Decreased appetite	CONCERTA	S				
Nausea	ADDERALL XR	S	UNKNOWN			
Dizziness	DAYTRANA	S	UNKNOWN			
Insomnia	VYVANSE	S	UNKNOWN			
Weight decreased	INTUNIV	S	UNKNOWN			
Increased appetite	STRATTERA	S	UNKNOWN			
Vision blurred	ABILIFY	S	UNKNOWN			
Hyperhidrosis	ZYPREXA	S	UNKNOWN			
Dyspepsia	ZYPREXA	S	UNKNOWN			
Somnolence	SEROQUEL	S	UNKNOWN			
	ANAFRANIL	S	UNKNOWN			
	ANAFRANIL	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	PROZAC	S	UNKNOWN			
	PROZAC	S	UNKNOWN			
	LUVOX	S	UNKNOWN			
	LUVOX	S	UNKNOWN			
	ZOLOFT	S	UNKNOWN			
	ZOLOFT	S	UNKNOWN			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Dec-2012	8955917	EXPEDITED (15-DAY)		HO	US-FRI-1000040917	47 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Back pain	LEXAPRO	S	ORAL	10 mg		FOREST
Sciatica	LUAF41156	S	ORAL	3 mg		
	LISINOPRIL	S	ORAL	20 mg		
	BABY ASPIRIN	C				
	LISINOPRIL/HCTZ	C				
	FLEXERIL	C				
	OXYCONTIN	C				
	OXYCODONE	C				
	NEURONTIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Dec-2012	8915777	EXPEDITED (15-DAY)		OT	JP-FRI-1000040465	73 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Haematuria	LEXAPRO	S	ORAL	10 mg		FOREST
Urinary retention	LENDORMIN	C	ORAL	0.25 mg		
	MAGMITT	C	ORAL	330 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Dec-2012	8960906	DIRECT	Y	OT			Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Unevaluable event	LEXAPRO	S	ORAL			
Drug intolerance						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Dec-2012	7376665	EXPEDITED (15-DAY)		DE,CA,OT	US-ABBOTT-10P-163-0640912-00		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hydrocephalus	HUMIRA 40 MG/ 0.8 ML PRE-FILLED SYRINGE	S	TRANSPLACENTAL			
Congenital heart valve disorder	LEXAPRO	S	TRANSPLACENTAL			
Tachypnoea	TRAZODONE	S	TRANSPLACENTAL			
Cytogenetic abnormality	ENBREL	S	TRANSPLACENTAL			
Hemivertebra	MUCINEX	S	TRANSPLACENTAL			
Cryptorchism	TUMS	S	TRANSPLACENTAL			
Kidney enlargement	TYLENOL	S	TRANSPLACENTAL			
Anal stenosis						
Atrial septal defect						
Cerebrospinal fluid leakage						
Coarctation of the aorta						
Foetal exposure during pregnancy						
Macrocephaly						
Neurodegenerative disorder						
Patent ductus arteriosus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Dec-2012	7523041	EXPEDITED (15-DAY)		HO	US-ABBOTT-10P-163-0640911-00	26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Caesarean section	HUMIRA 40 MG/ 0.8 ML PRE-FILLED SYRINGE	S	OTHER			
Fall	HUMIRA 40 MG/ 0.8 ML PRE-FILLED SYRINGE	S				
Urinary tract infection	LEXAPRO	S	ORAL			
	TRAZODONE HCL	C	ORAL	4 in one day as needed		
Dyspepsia	ENBREL	C	OTHER			
Fungal infection	MUCINEX	C	ORAL	1-2 pills QD		
Respiratory tract infection	PRENATAL VITAMINS	C		1 pill QD		
Premature delivery	CAFFEINE	C	ORAL	2.5 servings Mountain Dew daily		
Exposure during pregnancy	CAFFEINE	C	ORAL	5.67 servings Mountain Dew daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Dec-2012	8965568	DIRECT					Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	LEXAPRO	S				
Feeling abnormal						
Gait disturbance						
Speech disorder						

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Dec-2012	8965575	DIRECT		HO,DS,LT,OT		23 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mania	LEXAPRO	S	ORAL	20mg once daily po		FOREST
Abnormal behaviour						
Overdose						
Unevaluable event						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Dec-2012	8963070	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2012313677	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	Pristiq	S		50 mg, daily		PFIZER
Headache	Pristiq	S		100 mg, daily		PFIZER
Hypoaesthesia	PROZAC	S		UNK		
Rash	PROZAC	S				
Dermatitis	PAXIL	S		UNK		
Acne	PAXIL	S				
	CELEXA	S		UNK		
	CELEXA	S				
	LEXAPRO	S		UNK		
	LEXAPRO	S				
	WELLBATRIN	C		300 mg, daily		
	ADDERALL	C		30 mg, daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2012	8964168	NON-EXPEDITED			US-PFIZER INC-2012300299	44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Somnolence	OXYCODONE HYDROCHLORIDE	S	ORAL	15 mg, (ORAL EVERY 4 HRS AS NEEDED)		PFIZER
Blood pressure fluctuation	OXYCODONE HYDROCHLORIDE	S	ORAL	80 mg, 2x/day		PFIZER
Heart rate irregular	AMBIEN	S	ORAL	12.5 mg, (At bedtime)		
	LEXAPRO	S	ORAL	20 mg, daily		
	OXYCONTIN	S	ORAL	60 mg, 2x/day		
	SOMA	S	ORAL	350 mg, 2x/day		
	VALIUM	S	ORAL	10 mg, daily		
	XARELTO	S	ORAL	10 mg, daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2012	8965133	EXPEDITED (15-DAY)		CA	US-FRI-1000040942	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Talipes	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Dec-2012	8966757	EXPEDITED (15-DAY)		HO	AU-SANOFI-AVENTIS-2012SA090914	81 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Malaise	LASIX	S	UNKNOWN			
Abdominal pain	LASIX	S	UNKNOWN			
Urinary retention	LEXAPRO	S	ORAL			
Urine output decreased	FISH OIL	C				
Hyponatraemia	COUMADIN	C				
	CHONDROITIN W/GLUCOSAMINE	C				
	LANOXIN	C				
	LOSEC	C				
	PANADOL	C				
	FOLIC ACID/VITAMIN B12 NOS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8968383	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16766909	46 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abnormal behaviour	ABILIFY	S		Ablify 20mg cuts them in half for 10mg daily dose. started with 5mg		
Mood altered	LEXAPRO	S				
Abnormal dreams	KEPPRA	S				
	SYNTHROID	C				
	CLONAZEPAM	C				
	PAXIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8968390	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16770547	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dystonia	ABILIFY	S				
Dyskinesia	CONCERTA	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8968935	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16686867		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood cholesterol increased	ABILIFY	S				
	LEXAPRO	S				
	LAMICTAL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8968991	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16341877	17 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatic enzyme increased	ABILIFY	S	ORAL			
Nausea	LEXAPRO	S	ORAL			
Malaise						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8969178	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16299679	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Swelling	ABILIFY	S		5mg:Feb2011,Dose increased: 10mg,Mar2011, decreased later:2mg		
Tremor	LEXAPRO	S				
Ammonia increased	KEPPRA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8969374	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16625220		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tremor	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8969384	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16626129	24 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Akathisia	ABILIFY TABS 5 MG	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8969590	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16614141	45 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dysarthria	ABILIFY	S		Initially given 5mg then increased to 10mg		
	LEXAPRO	S				
	KLONOPIN	S		1mg in PM		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8969838	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16537342	6 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Weight increased	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8969864	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16544926		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspnoea	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8970001	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16525016	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Weight increased	ABILIFY TABS	S				
	LEXAPRO	S				
	KLONOPIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8970083	NON-EXPEDITED		OT	US-BRISTOL-MYERS SQUIBB COMPANY-16217523	15 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Clonic convulsion	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8970231	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16487878	69 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Asthenia	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8970392	NON-EXPEDITED		OT	US-BRISTOL-MYERS SQUIBB COMPANY-17057035		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diabetes mellitus	ABILIFY	S		1DF: upto 15mg		
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8970488	EXPEDITED (15-DAY)		OT	CN-FRI-1000041073	50 YR	Male	CHN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	LEXAPRO	S	ORAL	20 mg		FOREST
	LEXAPRO	S	ORAL	15 MG		FOREST
	LEXAPRO	S	ORAL	10 mg		
	BUSPIRONE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8970506	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16502742	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
White blood cell count decreased	ABILIFY	S				
	WELLBUTRIN	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8972962	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16458515	83 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vertigo	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8972970	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16461436	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Weight increased	ABILIFY	S				
	LEXAPRO	S				
	KLONOPIN	S				SANDOZ

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8973350	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16940629	32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyskinesia	ABILIFY	S	ORAL	from 06Jun2012:5mg Increased to 10mg/daily		
Swollen tongue	ABILIFY	S	ORAL	from 06Jun2012:5mg Increased to 10mg/daily		
Confusional state	ABILIFY	S	ORAL	from 06Jun2012:5mg Increased to 10mg/daily		
Dysarthria	LEXAPRO	S		Reduced to 5 mg		
Regurgitation	LEXAPRO	S		Reduced to 5 mg		
Tremor	LEXAPRO	S		Reduced to 5 mg		
	COGENTIN	S		on 07Jun2012 dose decreased to 1 mg/2/day		SANDOZ
	DEPAKOTE ER	C		250mg qam, 750 mg/2/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8973351	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16940884	44 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Somnolence	ABILIFY	S	ORAL			
	ABILIFY	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8973366	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16945958	64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Akathisia	ABILIFY	S				
	ABILIFY	S				
	LEXAPRO	S				
	LEXAPRO	S				
	VIIBRYD	S				
	VIIBRYD	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8973439	NON-EXPEDITED		OT	US-BRISTOL-MYERS SQUIBB COMPANY-16787723	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	ABILIFY	S	ORAL	increased to 15mg/day		
Libido decreased	CHANTIX	S		Restarted on 2011. Jul2012: 1mg		
Diarrhoea	GEODON	S				
Constipation	LEXAPRO	S				
Anxiety	XANAX	C				
Sleep disorder	LISINOPRIL	C		1 DF = 20/25 mg/daily		
Blood triglycerides increased						
Ejaculation disorder						
Muscle spasms						
Thirst						
Urinary retention						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8973471	NON-EXPEDITED		DE,OT	US-BRISTOL-MYERS SQUIBB COMPANY-16819112	16 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Completed suicide	ABILIFY	S		adjunctive therapy,Dose incd to 5mg until 18Apr12 Until 30Apr2012		
Anger	LEXAPRO	S		incr to 10mg-5Nov07 20mg-28Oct10 Until 30Apr2012		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8973860	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16895484	32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Disorientation	ABILIFY	S				
Dysarthria	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8973972	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16394827	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tardive dyskinesia	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8983975	DIRECT		HO,DS,OT			Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	LEXAPRO	S				
Drug prescribing error						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Dec-2012	8975034	EXPEDITED (15-DAY)		OT	US-FRI-1000041039		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mental impairment	LEXAPRO	S				FOREST
Abnormal dreams						
Depression						
Drug effect decreased						
Paraesthesia						
Suicidal ideation						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Dec-2012	8977083	EXPEDITED (15-DAY)		HO,LT	AU-FRI-1000041166		Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Obsessive-compulsive disorder	LEXAPRO	S	ORAL	5 mg		FOREST
Self injurious behaviour	LEXAPRO	S	ORAL	10 mg		FOREST
	LEXAPRO	S	ORAL	5 mg		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Dec-2012	8977417	NON-EXPEDITED			US-PFIZER INC-2012321662	40 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	GABAPENTIN	S		UNK		PFIZER
	LEXAPRO	S		UNK		
	HYTRIN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Dec-2012	8988340	DIRECT		LT,OT		41 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Homicidal ideation	LEXAPRO	S	ORAL			
Aggression						
Suicidal ideation						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Dec-2012	8905195	EXPEDITED (15-DAY)		HO	JP-FRI-1000040282	93 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hyponatraemia	LEXAPRO	S	ORAL	5 mg		FOREST
	LEXAPRO	S	ORAL	10 mg		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Dec-2012	8494340	EXPEDITED (15-DAY)		OT	JP-FRI-1000029490	52 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Electrocardiogram QT prolonged	LEXAPRO	S	ORAL	10mg		FOREST
Nausea	LEXAPRO	S	ORAL	10mg		FOREST
	MOSAPRIDE CITRATE HYDRATE	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Dec-2012	8990969	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Irritable bowel syndrome	LEXAPRO	S	ORAL	5 mg OD PO before 11/19/12		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Dec-2012	9298120	NON-EXPEDITED			PHEH2012US006354	17 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Emotional disorder	AFINITOR (RAD) UNKNOWN	S	ORAL			
Abnormal behaviour	CARBATROL (CARBAMAZEPINE)	S				
Mood altered	VITAMIN C (ASCORBIC ACID)	S				
Acne	LEXAPRO (ESCITALOPRAM OXALATE)	S				
Stomatitis	STRESS B (MINERALS NOS, VITAMINS NOS)	S				
Blood triglycerides increased	METFORMIN (METFORMIN)	S				
	RISPERDAL (RISPERIDONE)	S				
	SEROQUEL (QUETIAPINE FUMARATE)	S				
	NASONEX (MOMETASONE FUROATE)	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Dec-2012	8879988	EXPEDITED (15-DAY)		OT	IE-FRI-1000039958	46 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Arrhythmia	LEXAPRO	S	ORAL	10 mg		FOREST
Electrocardiogram QT prolonged						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Dec-2012	8990532	EXPEDITED (15-DAY)		HO	JP-FRI-1000028239		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Inappropriate antidiuretic hormone secretion	LEXAPRO	S	ORAL	10 mg		FOREST
Dizziness	LEXAPRO	S	ORAL	5 mg		FOREST
	RHEUMATREX	C	ORAL			
	REMICADE	C	INTRAVENOUS DRIP			
	DUROTEP	C	TOPICAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Dec-2012	8990654	EXPEDITED (15-DAY)		LT	JP-FRI-1000026517	35 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Loss of consciousness	LEXAPRO	S	ORAL	10 mg		FOREST
Bradycardia	LEXAPRO	S	ORAL	20 mg		FOREST
Headache	DOGMATYL	C	ORAL	150 mg		
Asthenia	WYPAX	C	ORAL	1.5 mg		
Parosmia	MYSLEE	C	ORAL	5 mg		
	DEPAS	C	ORAL	0.5 mg		
	LEXOTAN	C	ORAL	12 mg		
	ASUMEJI	C	ORAL			
	KIPRES	C	ORAL	10 mg		
	TAKEPRON	C	ORAL	30 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Dec-2012	8990659	EXPEDITED (15-DAY)		OT	JP-FRI-1000025239	38 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hyperventilation	LEXAPRO	S	ORAL	10 mg		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2013	8725431	EXPEDITED (15-DAY)		HO	JP-FRI-1000037747	77 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cholestasis	LEXAPRO	S	ORAL	10 mg		FOREST
Drug eruption	PAXIL	S	ORAL	10 mg		
Blood glucose increased	PAXIL	S	ORAL	20 mg		
	PAXIL	S	ORAL	10 mg		
	TEGRETOL	S	ORAL	200 mg		
	CEPHADOL	C	ORAL	75 mg		
	DEPAS	C	ORAL	0.5 mg		
	BAYASPIRIN	C	ORAL	100 mg		
	TAKEPRON	C	ORAL	15 mg		
	PANTOSIN	C	ORAL	3 g		
	MAGNESIUM OXIDE	C	ORAL	1.5 g		
	AFTACH	C	OTHER	25 mcg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2013	8993300	NON-EXPEDITED			US-PFIZER INC-2012332632	46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	Pristiq	S		100 mg, UNK		PFIZER
Lethargy	Effexor XR	S		UNK		PFIZER
Loss of libido	WELLBUTRIN	S		UNK		
Fatigue	PAXIL	S		UNK		
Weight increased	LEXAPRO	S		UNK		
Agoraphobia						
Anxiety						
Appetite disorder						
Cough						
Depression						
Diarrhoea						
Fear						
Feeling abnormal						
Headache						
Nasopharyngitis						
Nausea						
Obsessive thoughts						
Paraesthesia						
Withdrawal syndrome						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Jan-2013	8990312	EXPEDITED (15-DAY)		OT	JP-FRI-1000041292		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Loss of consciousness	LEXAPRO	S	ORAL			FOREST
Initial insomnia	GANATON	C	ORAL			
Asthenia	LENDORMIN	C	ORAL			
Malaise	DEPAS	C	ORAL			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jan-2013	9013252	DIRECT	Y	DS		16 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chills	LEXAPRO	S	ORAL			
	MEDROL	C				
	KENALOG	C				
Akathisia	CYMBALTA	C				
Anxiety						
Arthralgia						
Back pain						
Blood pressure increased						
Breast disorder						
Breast tenderness						
Decreased appetite						
Diarrhoea						
Disinhibition						
Disturbance in attention						
Dizziness						
Dyspepsia						
Eructation						
Headache						
Hyperacusis						
Hyperaesthesia						
Hyperhidrosis						
Hypoaesthesia						
Irritability						
Memory impairment						
Mydriasis						
Pain in extremity						
Panic attack						
Photophobia						
Pollakiuria						
Tremor						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jan-2013	9500435	EXPEDITED (15-DAY)	Y	OT	PHEH2012US017443	47 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	GILENYA (FTY)CAPSULE	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jan-2013	9003663	NON-EXPEDITED			US-GLAXOSMITHKLINE-A0957113A	76 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dysgeusia	LOVAZA	S	ORAL	4CAP Per day		GLAXOSMITHKLINE
Ageusia	LEXAPRO	S	ORAL	1TAB Per day		
Erectile dysfunction	ANDROGEL	C				
	Zocor	C				GLAXOSMITHKLINE
	Hyzaar	C				
	Niacin	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jan-2013	9009738	EXPEDITED (15-DAY)		CA	US-FRI-1000041471		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cleft lip and palate	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jan-2013	9009957	EXPEDITED (15-DAY)		CA	US-FRI-1000028948	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Patent ductus arteriosus	LEXAPRO	S	TRANSPLACENTAL			FOREST
Bicuspid aortic valve						
Congenital anomaly						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jan-2013	9009973	EXPEDITED (15-DAY)		CA	US-FRI-1000041469	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Limb reduction defect	LEXAPRO	S	TRANSPLACENTAL			FOREST
Atrial septal defect						
Congenital anomaly						
Patent ductus arteriosus						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jan-2013	8926768	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2012294611	48 YR	Female	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	Efexor XR	S	ORAL	1 capsule (75 mg), 1x/day		PFIZER
Asphyxia	Efexor XR	S		1 capsule (75 mg), 2x/day		PFIZER
Dyspnoea	Efexor XR	S		1 capsule (75mg) and 1 capsule (37.5mg) a day		PFIZER
Confusional state	Efexor XR	S	ORAL	37.5 mg, UNK		PFIZER
Chest pain	CITALOPRAM	S		UNK		
Heart rate increased	LEXAPRO	S		half tablet of 10mg (5mg), 1x/day		
Feeling abnormal	STILNOX	C		UNK		
Amnesia						
Feeling abnormal						
Mania						
Panic disorder						
Uterine disorder						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jan-2013	9008345	NON-EXPEDITED			US-PFIZER INC-2013011779		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	Lyrica	S		50 mg, 2x/day		PFIZER
	Lyrica	S		100 mg, 2x/day		PFIZER
	OXYCODONE HYDROCHLORIDE	S		UNK		PFIZER
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jan-2013	9018208	DIRECT	Y	RI		69 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depressed mood	LEXAPRO	S	ORAL	20mg 1/2 tab. a day po	2 MTH	
Activities of daily living impaired	ESCITALOPRAM	C				
Abdominal discomfort						
Disease recurrence						
Insomnia						
Palpitations						
Panic attack						
Product substitution issue						
Visual impairment						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2013	9008251	EXPEDITED (15-DAY)	Y	HO,OT	THQ2012A11181	41 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ventricular fibrillation	TAKEPRON	S	ORAL			
Cardiac failure	LAMICTAL (LAMOTRIGINE)	C				
Apathy	LANDSEN (CLONAZEPAM)	C				
Electrocardiogram R on T phenomenon	RIVOTRIL (CLONAZEPAM)	C				
Loss of consciousness	PLAVIX (CLOPIDOGREL BISULFATE)	C				
Coronary artery occlusion	BAYASPIRIN (ACETYLSALICYLIC ACID) (ACETYLSALICYLIC ACID)	C				
Blood calcium decreased	CRESTOR (ROSUVASTATIN CALCIUM)	C				
Acute myocardial infarction	NICORANDIS (NICORANDIL)	C				
Ventricular extrasystoles	MAGNESIUM OXIDE	C				
	SOLITA (SODIUM LACTATE, POTASSIUM CHLORIDE, CALCIUM CHLORIDE DIHYDRATE)	C				
	HEPARIN SODIUM	C				
Blood potassium abnormal						
Drug interaction						
Extrasystoles						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2013	9013047	NON-EXPEDITED			US-PFIZER INC-2013011896	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Burning sensation	Lyrica	S	ORAL	50 mg, 2x/day		PFIZER
Insomnia	Lyrica	S	ORAL	50 mg, 2x/day		PFIZER
Anxiety	Lyrica	S	ORAL	100 mg, 2x/day		PFIZER
	LEXAPRO	S		10 mg, daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2013	7868619	EXPEDITED (15-DAY)		OT	US-RB-024190-11		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abortion spontaneous	Suboxone Tablet	S	SUBLINGUAL			RECKITT BENCKISER
Exposure during pregnancy	Subutex	S	SUBLINGUAL			RECKITT BENCKISER
	Lexapro	S	UNKNOWN	Dosage information unknown- 20 milligrams daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2013	9015979	EXPEDITED (15-DAY)		OT	US-FRI-1000041583		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug interaction	LEXAPRO	S				FOREST
Loss of consciousness	CYMBALTA	S				
Contusion						
Cough						
Fall						
Oral fungal infection						
Periorbital haematoma						
Skin burning sensation						
Syncope						
Urinary incontinence						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2013	9016533	EXPEDITED (15-DAY)		HO,OT	US-009507513-1301USA 003476		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Urinary tract infection	SINGULAIR	S		10 mg, UNK		MERCK
Migraine	MIRAPEX	S		0.75 mg, (0.25 mg and 0.5 mg)		
Infection	AMBIEN	S		5 mg, qd		
Fall	ADDERALL TABLETS	S		10 mg, bid		
Dehydration	LYRICA	S		100 mg, tid		
Balance disorder	LEXAPRO	S		20 mg, qd		
	nitrofurantoin	S		100 mg, bid		
	loratadine	S		10 mg, UNK		
	GILENYA	S	ORAL	0.5 mg, qd		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2013	9124308	NON-EXPEDITED			US-PFIZER INC-2013016923		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	Lyrica	S		UNK		PFIZER
	LEXAPRO	S		10 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jan-2013	8554650	EXPEDITED (15-DAY)			JP-FRI-1000030371		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	LEXAPRO	S	ORAL			FOREST
Corneal reflex decreased						
Excessive eye blinking						
Headache						
Muscle rigidity						
Paraesthesia						
Tremor						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jan-2013	9019641	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16680480	6 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vomiting	ABILIFY	S	ORAL			
Decreased appetite	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jan-2013	9036764	DIRECT	Y	OT		11 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depressed mood	LEXAPRO	S	ORAL			
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jan-2013	9036800	DIRECT				70 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vertigo	LEXAPRO	S	ORAL			AUROBINDO
Dizziness						
Fall						
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jan-2013	9025252	EXPEDITED (15-DAY)		CA	US-FRI-1000041755	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Craniosynostosis	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2013	9027365	EXPEDITED (15-DAY)		CA	US-FRI-1000041764	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Arnold-Chiari malformation	LEXAPRO	S	TRANSPLACENTAL			FOREST
Cerebral palsy						
Congenital hydrocephalus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jan-2013	8961243	EXPEDITED (15-DAY)		LT,OT	PHEH2012US024269		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Malaise	VIVELLE DOT	S	TRANSDERMAL	0.025 mg, QW2 (twice weekly)		NOVARTIS
Malignant melanoma	CAFERGOT	S				
Thyroid disorder	AMOXAPINE	S				
Drug hypersensitivity	LEXAPRO	S				
	CODEINE	S				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2013	8969971	EXPEDITED (15-DAY)		HO,OT	US-ELI_LILLY_AND_COMPANY-US201212003168		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Syncope	CYMBALTA	S		60 mg, qd		ELI LILLY AND CO
Chronic obstructive pulmonary disease	LEXAPRO	S		UNK, unknown		
Loss of consciousness	HYDROCODONE	C		UNK, unknown		
Fall	KLONOPIN	C		UNK, unknown		
Drug interaction	DEXLANSOPRAZOLE	C		UNK, unknown		
Contusion						
Convulsion						
Cough						
Excoriation						
Periorbital contusion						
Urinary incontinence						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2013	9038122	EXPEDITED (15-DAY)		HO,OT	US-GLAXOSMITHKLINE-A0958320A	36 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	Wellbutrin	S		300MG Twice per day		GLAXOSMITHKLINE
Atrial fibrillation	Effexor	S				GLAXOSMITHKLINE
Myocardial infarction	Ambien	S				
Suicide attempt	Zyprexa	S				GLAXOSMITHKLINE
Nasopharyngitis	LEXAPRO	S				
Panic attack	Adderall	S				
Stress	Concerta	S				GLAXOSMITHKLINE
Ill-defined disorder	Ativan	S	UNKNOWN			
	Depakote	S	UNKNOWN			
	Trileptal	S	UNKNOWN			
	LITHIUM	S	UNKNOWN			GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2013	9038131	NON-EXPEDITED			US-GLAXOSMITHKLINE-A0960858A		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Adverse event	Wellbutrin	S	UNKNOWN			GLAXOSMITHKLINE
	LEXAPRO	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2013	9038176	NON-EXPEDITED			US-GLAXOSMITHKLINE-A0975005A		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anger	Wellbutrin	S	ORAL			GLAXOSMITHKLINE
Therapeutic response decreased	LEXAPRO	S	UNKNOWN			
Weight increased	Crestor	C				GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2013	9038186	NON-EXPEDITED			US-GLAXOSMITHKLINE-A0977564A		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Alopecia	Wellbutrin	S	ORAL	150MG Per day		GLAXOSMITHKLINE
	LEXAPRO	S	ORAL	10MG Per day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2013	9041863	NON-EXPEDITED			US-ABBOTT-12P-163-0893986-00		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Skin irritation	HUMIRA 40 MG/0.8 ML PEN	S		80 mg Once		
Rash	HUMIRA 40 MG/0.8 ML PEN	S				
Rash	HUMIRA 40 MG/0.8 ML PEN	S				
Nasopharyngitis	LEXAPRO	S				
Skin irritation	XANAX	C				
	ASPIRIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2013	9052001	DIRECT				27 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	LEXAPRO	S		Lexapro 5 mg daily 6/12 - current		
Condition aggravated						
Mood altered						
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2013	9076209	NON-EXPEDITED			US-ABBOTT-12P-163-0952017-00	68 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Parkinsonism	HUMIRA 40 MG/0.8 ML PEN	S				
Injection site pruritus	SINEMET	S		25/100mg TID to 25/100mg 2 tab TID to 1 tab TID		
Injection site erythema	LEXAPRO	S				
Pain in extremity	PROAIR	C	INHALATION			
Pain	FLOVENT DISKUS	C				
Muscular weakness	TYLENOL EXTRA STRENGTH	C				
Fall	CALCIUM NASAL SPRAY	C		Daily		
Pain	LASIX	C		Daily		
Rheumatoid arthritis	LEVOTHYROXIN	C		Daily		
Rash papular	METOPROLOL	C				
Rash papular	ESTROPIPATE	C		Daily		
Rash papular	KLONOPIN	C				
Injection site erythema						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2013	9077123	NON-EXPEDITED			US-ABBOTT-12P-163-0938654-00	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HUMIRA 40 MG/0.8 ML PEN	S				
Injection site haemorrhage	LEXAPRO	S				
	ZYRTEC	C		daily		
	BENADRYL	C		daily		
	BIRTH CONTROL PILL	C				
	LEXAPRO	C		10mg daily		
	LEXAPRO	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2013	8459297	EXPEDITED (15-DAY)		OT	JP-FRI-1000029057		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Visual acuity reduced	LEXAPRO	S	ORAL	10 mg		FOREST
	LEXAPRO	S		20 mg		FOREST
	MYSLEE	C	ORAL			
	MEILAX	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2013	9079033	EXPEDITED (15-DAY)		CA	US-FRI-1000042154	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Coarctation of the aorta	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2013	9079055	EXPEDITED (15-DAY)		DE	US-FRI-1000042216	26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Death	LEXAPRO	S				FOREST
	HYDROCODONE	S				
	ALCOHOL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2013	9079181	EXPEDITED (15-DAY)		OT	BR-FRI-1000042213		Female	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Asphyxia	LEXAPRO	S	ORAL	5 mg		FOREST
Suicidal ideation	LEXAPRO	S	ORAL	10 mg		
Chest pain	EFEXOR XR	C	ORAL	75 mg		
Tachycardia	STILNOX	C				
Feeling abnormal	RIVOTRIL	C	ORAL			
Confusional state						
Dyspnoea						
Mania						
Panic attack						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2013	8907373	EXPEDITED (15-DAY)		HO	AU-FRI-1000040355	81 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hyponatraemia	LEXAPRO	S	ORAL	10 mg		FOREST
Urinary retention	LASIX	S				
Abdominal pain	LOSEC	C				
Urine output decreased	BLACKMORES FISH OIL	C				
Malaise	COUMADIN	C				
	GLUCOSAMINE-CHONDROITIN	C				
	LANOXIN	C				
	PANADOL OSTEO	C				
	VITAMIN B12 NOS	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2013	9049059	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-17316720	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mania	ABILIFY TABS 5 MG	S				
Arthralgia	LEXAPRO	S				
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Feb-2013	9120032	EXPEDITED (15-DAY)		HO,OT	PHEH2013US002804		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicide attempt	FEMARA	S		2.5 mg, QD		NOVARTIS
Lymphoedema	ZOMETA	S		UNK UKN, UNK		
Tardive dyskinesia	ARIMIDEX	S		UNK UKN, UNK		
Tooth fracture	LEXAPRO	S		UNK UKN, UNK		
Renal impairment	TAMOXIFEN	C		UNK UKN, UNK		
Depression	TOREMIFENE	C		UNK UKN, UNK		
Breast cancer	WELLBUTRIN XR	C		UNK UKN, UNK		
Malignant neoplasm progression	TAXOL	C		UNK UKN, UNK		
Metastases to bone	GEMCITABINE	C		UNK UKN, UNK		
Nausea	NAVELBINE	C		UNK UKN, UNK		
Headache	VITAMIN D3	C		UNK UKN, UNK		
Asthenia	COZAAR	C		UNK UKN, UNK		
Fatigue	METFORMIN	C		UNK UKN, UNK		
Pallor	OMEPRAZOLE	C		UNK UKN, UNK		
Arthralgia	SENNA	C		UNK UKN, UNK		
	ATENOLOL	C		UNK UKN, UNK		
	ZOFRAN	C		UNK UKN, UNK		
	NAPROSYN	C		UNK UKN, UNK		
	COMPAZINE	C		UNK UKN, UNK		
	TRAZODONE	C		UNK UKN, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Feb-2013	8895875	EXPEDITED (15-DAY)		HO	JP-FRI-1000040172	21 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Agitation	LEXAPRO	S	ORAL			FOREST
Delirium						
Hyperthyroidism						
Overdose						
Tachycardia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Feb-2013	9117247	EXPEDITED (15-DAY)		OT	US-FRI-1000042420	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Retinal detachment	LEXAPRO	S				FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Feb-2013	8988918	EXPEDITED (15-DAY)		OT	US-FRI-1000041249	64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anal haemorrhage	LEXAPRO	S	ORAL	10 mg		FOREST
Gastric dilatation	LEXAPRO	S	ORAL	10 mg QOD		FOREST
Off label use	ASPIRIN	C				
	LEVOTHYROXINE	C		50 mcg		
	VITAMIN B12	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Feb-2013	9058949	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16432361	76 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug eruption	METFORMIN HCL	S				BRISTOL MYERS SQUIBB
	PLAVIX	S				SANOFI AVENTIS
	PLAVIX	S				SANOFI AVENTIS
	RAMIPRIL	S				
	FUROSEMIDE	S				
	SIMVASTATIN	S				
	LEXAPRO	S				
	FOLIC ACID	S				
	AMLODIPINE	S				
	METOPROLOL SUCCINATE	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2013	9097703	EXPEDITED (15-DAY)		OT	US-FRI-1000042506		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Haemorrhagic stroke	LEXAPRO	S				FOREST
Asthenia	LEXAPRO	S				FOREST
Coordination abnormal	INTERFERON	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2013	9092584	DIRECT		OT		38 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Paraesthesia	CYMBALTA	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2013	9098726	EXPEDITED (15-DAY)		CA	US-FRI-1000042538	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Multiple cardiac defects	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2013	9098727	EXPEDITED (15-DAY)		CA	US-FRI-1000042516	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Heterotaxia	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						
Developmental delay						
Pulmonary artery atresia						
Transposition of the great vessels						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Feb-2013	9066464	EXPEDITED (15-DAY)		HO	IE-FRI-1000042579		Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Low birth weight baby	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Feb-2013	9094909	DIRECT		DE,LT,OT		66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chest pain	LEXAPRO	S	ORAL	10mg? once daily? po		FOREST
Agitation						
Confusional state						
Disorientation						
Unresponsive to stimuli						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Feb-2013	8455433	EXPEDITED (15-DAY)		OT	JP-FRI-1000028582	33 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertriglyceridaemia	LEXAPRO	S	ORAL	20 mg		FOREST
Liver disorder	TAPIZOL	S	ORAL	10 mg		
Aspartate aminotransferase increased	ABILIFY	S	ORAL	3 mg		
Alanine aminotransferase increased	DOGMATYL	S	ORAL	100 mg		
Blood alkaline phosphatase increased	MEILAX	C	ORAL	2 mg		
Blood cholesterol increased	FLUNITRAZEPAM	C	ORAL	1 mg		
	RIZE	C	ORAL			
	PODONIN-S	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2013	9105954	EXPEDITED (15-DAY)		HO,LT	AU-FRI-1000042748	25 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Self injurious behaviour	LEXAPRO	S	ORAL	5 mg		FOREST
Obsessive-compulsive disorder	LEXAPRO	S	ORAL	10 mg		FOREST
	LEXAPRO	S	ORAL	5 mg		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Feb-2013	9075985	EXPEDITED (15-DAY)		DE,CA,OT	US-FRI-1000041995	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrial septal defect	LEXAPRO	S	TRANSPLACENTAL			FOREST
Multiple cardiac defects	ZOLOFT	S	TRANSPLACENTAL			
Persistent foetal circulation	PRENATAL VITAMIN	S	TRANSPLACENTAL			
Cleft lip						
Cleft palate						
Congenital anomaly						
Cytogenetic abnormality						
Deafness						
Double outlet right ventricle						
Exomphalos						
Lung disorder						
Neural tube defect						
Pulmonary artery stenosis congenital						
Talipes						
Transposition of the great vessels						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Feb-2013	9108605	EXPEDITED (15-DAY)		CA	US-FRI-1000042856	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Talipes	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						
Gastrooesophageal reflux disease						
Patent ductus arteriosus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Feb-2013	9119453	DIRECT	Y	OT		52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Irritability	LEXAPRO	S	ORAL	10 mg. daily po		TEVA
Tension						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2013	8012810	EXPEDITED (15-DAY)		DE,HO,CA,OT	US-PFIZER INC-2011139942	2 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Foetal exposure during pregnancy	Zoloft	S	TRANSPLACENTAL	50 mg, 1x/day		PFIZER
Aortic stenosis	LEXAPRO	S	TRANSPLACENTAL	UNK		
Left ventricular dysfunction	HYDROXYZINE	C	TRANSPLACENTAL	UNK		
Left ventricular failure	AMOXIL	C	TRANSPLACENTAL	UNK		
Patent ductus arteriosus	CHROMAGEN OB	C	TRANSPLACENTAL	UNK		
Pulmonary valve stenosis	NAPROXEN SODIUM S	C	TRANSPLACENTAL	UNK		
Pulmonary valve incompetence	NISTATIN	C	TRANSPLACENTAL	UNK		
Intracranial venous sinus thrombosis	DULCOLAX	C	TRANSPLACENTAL	UNK		
Endocarditis	SERAX	C	TRANSPLACENTAL	15 mg, 1x/day		
Mediastinal haemorrhage	PROMETHAZINE	C	TRANSPLACENTAL	UNK		
Extracorporeal membrane oxygenation	HYDROCODONE W/ ACETAMINOPHEN	C	TRANSPLACENTAL	UNK		
Aortic valve disease mixed	ORTHO TRI CYCLEN	C	TRANSPLACENTAL	UNK		
Bicuspid aortic valve	PALGIC DS	C	TRANSPLACENTAL	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2013	8468684	EXPEDITED (15-DAY)			JP-FRI-1000029186	33 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood creatine phosphokinase increased	LEXAPRO	S	ORAL	20 mg		FOREST
	MYSLEE	C	ORAL	10 mg		
	RIZE	C	ORAL	10 mg		
	GOODMIN	C	ORAL	0.25 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2013	9121472	NON-EXPEDITED			US-PFIZER INC-2013065355	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Paraesthesia oral	Protonix	S		UNK		PFIZER
Dysgeusia	BENADRYL	S		UNK		
	LEXAPRO	S		UNK		
	KLONOPIN	S		UNK		
	VITAMIN D	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2013	9119862	EXPEDITED (15-DAY)		DS,OT	BR-ASTRAZENECA-2013SE11396		Female	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pulmonary embolism	SEROQUEL	S	ORAL			ZENECA
Foot fracture	LEXAPRO	S	UNKNOWN			
	UNSPECIFIED INGREDIENT	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2013	9145625	DIRECT		OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	LEXAPRO	S	ORAL			
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2013	9145981	DIRECT	Y	OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hallucination	CELEXA	S				
Nausea	PAXIL	S				
Vomiting	LEXAPRO	S				
Panic attack	CITALOPRAM	S				
Drug ineffective	SERTRALINE	S				
	ZOLOFT	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Feb-2013	9050662	EXPEDITED (15-DAY)		HO,OT	JP-FRI-1000042409		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug-induced liver injury	LEXAPRO	S	ORAL	10 mg		FOREST
	LITHIUM CARBONATE	S	ORAL	800 mg		
	AMOXAN	C	ORAL	100 mg		
	CRESTOR	C	ORAL	2.5 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Feb-2013	9127973	EXPEDITED (15-DAY)		CA	US-FRI-1000042932	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Transposition of the great vessels	LEXAPRO	S	TRANSPLACENTAL			FOREST
Atrial septal defect						
Multiple congenital abnormalities						
Patent ductus arteriosus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2013	9137753	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-PERC20110027	37 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug interaction	PERCOCET	S	ORAL	10/625 MG		
Panic attack	LEXAPRO	S	ORAL			
	LORTAB	C	ORAL	UNK		
	DEXTROAMPHETAMINE	C		UNK		
	CLONAZEPAM	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2013	9138775	NON-EXPEDITED		DE	US-ENDO PHARMACEUTICALS INC.-PERC20110001	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebrovascular accident	PERCOCET-5	S	ORAL	5/325 MG		
Drug abuse	PERCOCET-5	S				
Chest pain	LEXAPRO	S	ORAL			
	SOMA	S	ORAL			
	SOMA	S				
	VALIUM	S		UNK		
	FENTORA	S	BUCCAL			
	FENTORA	S				
	FENTANYL	S	TRANSDERMAL	UNK		
	FENTANYL	S				
	ZIPSOR	S	ORAL	25 MG		
	ZIPSOR	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2013	9139672	NON-EXPEDITED			US-PFIZER INC-2013073565	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Psychiatric symptom	Zoloft	S		UNK		PFIZER
Memory impairment	CELEXA	S		UNK		
	PROZAC	S		UNK		
	LEXAPRO	S		UNK		
	PAXIL	S		UNK		
	TRAZODONE	S		UNK		
	WELLBUTRIN	S		UNK		
	CYMBALTA	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2013	9252320	NON-EXPEDITED	Y	DS	163-21880-12083000	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	REVLIMID (LENALIDOMIDE) (5 MILLIGRAM, CAPSULES)	S	ORAL	5 mg, 1 in 1 D, PO		
Oedema peripheral	DEXAMETHASONE (DEXAMETHASONE)	S				
	ASPIRIN (ACETYLSALICYLIC ACID)	S				
	LIPITOR (ATORVASTATIN) (40 MILLIGRAM, TABLETS)	S				
	CALCIUM (CALCIUM)	S				
	COREG (CARVEDILOL)	S				
	CENTRUM (CENTRUM) (TABLETS)	S				
	FRAGMIN (HEPARIN-FRACTION, SODIUM SALT)	S				
	ALLOPURINOL (ALLOPURINOL) UNKNOWN	S				
	ERGOCALCIFEROL (ERGOCALCIFEROL)	S				

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	LEXAPRO (ESCITALOPRAM OXALATE)	S				
	GEMFIBROZIL (GEMFIBROZIL)	S				
	HYDROCODONE / ACETAMINOPHEN (REMEDEINE)	S				
	HYDROXYZINE (HYDROXYZINE)	S				
	KEPPRA (LEVETIRACETAM)	S				
	MAGNESIUM OXIDE (MAGNESIUM OXIDE) (500 MILLIGRAM, TABLETS)	S				
	RITALIN (METHYLPHENIDATE HYDROCHLORIDE)	S				
	NORTRIPTYLINE (NORTRIPTYLINE)	S				
	PROTONIX	S				
	PHENERGAN (PROMETHAZINE)	S				
	MAXALT (RIZATRIPTAN BENZOATE)	S				
	VALTREX (VALCICLOVIR HYDROCHLORIDE)	S				
	VITAMIN D (ERGOCALCIFEROL) (CAPSULES)	S				
	PLATELETS (PLATELETS)	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2013	9252440	NON-EXPEDITED	Y	HO,OT	163-21880-12083020	46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Herpes zoster	REVLIMID	S	ORAL	25 mg, 1 in 1 D, po		
Thrombosis	VALACYCLOVIR	S				
	PROCHLORPERAZINE	S				
	OXYCONTIN (OXYCODONE HYDROCHLORIDE)	S				
	ENOXAPARIN (ENOXAPARIN)	S				
	OXYCODONE (OXYCODONE)	S				
	LEXAPRO	S				
	PROTONIX	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2013	8442926	EXPEDITED (15-DAY)		DE,OT	JP-FRI-1000028810	79 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Interstitial lung disease	LEXAPRO	S	ORAL	10 mg		FOREST
Pneumothorax	KEISHI-KA-SHAKUYAKU-TO	S	ORAL			
Pneumonia aspiration	GANATON	C	ORAL			
	MYSLEE	C	ORAL			
	YODEL-S	C	ORAL			
	CELECOX	C	ORAL	200 mg		
	TAKEPRON	C	ORAL	30 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2013	9030466	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013024458	43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Off label use	Pristiq	S	ORAL	UNK		PFIZER
Depression	Pristiq	S	ORAL	50 mg, 2x/day		PFIZER
Drug ineffective	Pristiq	S	ORAL	50 mg, 3x/day		PFIZER
Social fear	Pristiq	S	ORAL	100 mg, 2x/day		PFIZER
Crying	Pristiq	S	ORAL	100mg morning, 50mg afternoon and 100mg night		PFIZER
	Pristiq	S	ORAL	50 mg, five times daily		PFIZER
	Zoloft	S		UNK		PFIZER
	LITHIUM CARBONATE	S		300 mg, 3x/day		PFIZER
	PROZAC	S		UNK		
	LAMICTAL	S		UNK		
	WELLBUTRIN	S		UNK		
	LEXAPRO	S		UNK		
	ABILIFY	S		10 mg,daily		
	TOPAMAX	S		UNK		
	KLONOPIN	S		UNK		
	VALIUM	S		UNK		
	PAXIL	S		UNK		
	CELEXA	S		UNK		
	CYMBALTA	S		UNK		
	ANAFRANIL	S		UNK		
	IMIPRAMINE	S		UNK		
	TEGRETOL	S		UNK		
	LUVOX	S		UNK		
	SEROQUEL	S		UNK		
	DEPAKOTE	S		UNK		
	SEROQUEL XR	C		250 mg, daily		
	XANAX	C		0.5 mg, as needed		
	ADDERALL	C		5 mg, 2x/day		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Mar-2013	6679655	EXPEDITED (15-DAY)		DE,HO,CA,OT	US-PFIZER INC-2008049876		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Foetal exposure during pregnancy	Zoloft	S	TRANSPLACENTAL	50 mg, 1x/day		PFIZER
Multiple congenital abnormalities	Zoloft	S				PFIZER
Mitral valve hypoplasia	LEXAPRO	S	TRANSPLACENTAL	10 mg, 1x/day		
Aortic valve stenosis	PRENATAL VITAMINS	C	TRANSPLACENTAL	UNK		
Persistent foetal circulation	REGLAN	C	TRANSPLACENTAL	10 mg, UNK		
Atrioventricular septal defect	ZYRTEC	C	TRANSPLACENTAL	10 mg, UNK		
Patent ductus arteriosus	BENADRYL	C	TRANSPLACENTAL	UNK		
Hypoplastic left heart syndrome	TYLENOL	C	TRANSPLACENTAL	UNK		
Right ventricular hypertrophy	ROBITUSSIN "ROBINS"	C	TRANSPLACENTAL	UNK		
Hepatic congestion	Z-PAK	C	TRANSPLACENTAL	UNK		
Renal tubular necrosis	KAOPECTATE	C	TRANSPLACENTAL	UNK		
Lung disorder	DARVOCET	C	TRANSPLACENTAL	UNK		
	CEPHALEXIN	C	TRANSPLACENTAL	500 mg, UNK		
	ZITHROMAX	C	TRANSPLACENTAL	250 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Mar-2013	9148817	EXPEDITED (15-DAY)		OT	US-JNJFOC-20130216891		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nephrolithiasis	TOPAMAX	S	ORAL			
Musculoskeletal pain	TOPAMAX	S	ORAL			
Depression	TOPAMAX	S	ORAL			
Neoplasm	TOPAMAX	S	ORAL			
Abnormal loss of weight	GABAPENTIN	S	UNKNOWN			
Memory impairment	LYRICA	S	UNKNOWN			
Influenza like illness	LEXAPRO	S	UNKNOWN			
Nausea	SYNTHROID	C	ORAL			
Alopecia						
Hair texture abnormal						
Migraine						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Mar-2013	9152543	EXPEDITED (15-DAY)		HO	JP-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-BI-05552NB	82 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hyponatraemia	MICARDIS	S	ORAL			BOEHRINGER INGELHEIM
	LEXAPRO	S	ORAL			
	FLUITRAN	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Mar-2013	9157279	DIRECT		OT		22 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dizziness	LEXAPRO	S				
Disturbance in attention						
Feeling abnormal						
Hallucination						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Mar-2013	9157424	DIRECT		OT		71 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Feeling hot	LEXAPRO / FOREST PHARMACE	S		Took 1/2 TAB 20 MG 1X DAY		FOREST
Anxiety						
Asthenia						
Blood pressure fluctuation						
Blood pressure increased						
Dizziness						
Headache						
Heart rate abnormal						
Musculoskeletal stiffness						
Nausea						
Paraesthesia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Mar-2013	8301396	EXPEDITED (15-DAY)		CA,OT	US-RB-035466-11		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Foetal exposure during pregnancy	Suboxone film	S	TRANSPLACENTAL	Suboxone film		RECKITT BENCKISER
Cleft palate	Lexapro	S	TRANSPLACENTAL			
	CANNABIS SATIVA SUBSP. INDICA TOP	S	TRANSPLACENTAL	Dosing details unknown		
	Benzodiazepines	S	TRANSPLACENTAL	Dosing details unknown		
	Opiates	S	TRANSPLACENTAL	Dosing details unknown		
	Nicotine	S	TRANSPLACENTAL	Dosing details unknown		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Mar-2013	9154925	NON-EXPEDITED			US-ABBOTT-12P-163-0967412-00		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Off label use	LUPRON DEPOT 11.25 MG	S	INTRAMUSCULAR			
Abnormal dreams	LEXAPRO	S				
Mood altered	DEPAKOTE	C				
	TOPROL XL	C				
	ZONISAMIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2013	7853856	NON-EXPEDITED			US-ABBOTT-10P-163-0640781-00	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Trismus	DEPAKOTE	S	ORAL			
Somnolence	DEPAKOTE	S	ORAL			
Trismus	DEPAKOTE	S				
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	SEROQUEL	S	ORAL			
	SEROQUEL	S	ORAL			
	SEROQUEL	S	ORAL			
	SYNTHROID	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2013	9002329	EXPEDITED (15-DAY)		OT	JP-FRI-1000040680	82 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Long QT syndrome	LEXAPRO	S	ORAL	20 mg		FOREST
Ventricular extrasystoles	BETAMAC	S	ORAL	150 mg		
	SOLANAX	C	ORAL	1.2 mg		
	MYSLEE	C	ORAL	10 mg		
	MEXITIL	C	ORAL	150 mg		
	DIOVAN	C	ORAL	40 mg		
	ACTONEL	C	ORAL	2.5 mg		
	MAGMITT	C	ORAL	990 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2013	9161503	EXPEDITED (15-DAY)		CA	US-FRI-1000043263	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Spina bifida	LEXAPRO	S				FOREST
	CELEXA	S				FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Mar-2013	9163501	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013084207	38 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrial fibrillation	Effexor	S		UNK		PFIZER
Myocardial infarction	Ativan	S		UNK		PFIZER
Suicide attempt	LITHIUM CARBONATE	S		UNK		PFIZER
Imprisonment	WELLBUTRIN	S		UNK		
Panic attack	CONCERTA	S		UNK		
Nasopharyngitis	DEPAKOTE	S		UNK		
	TRILEPTAL	S		UNK		
	LEXAPRO	S		UNK		
	AMBIEN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Mar-2013	9163674	EXPEDITED (15-DAY)		CA	US-FRI-1000043278	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Coarctation of the aorta	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Mar-2013	9163692	EXPEDITED (15-DAY)		CA	US-FRI-1000043270	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Talipes	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Mar-2013	9163802	EXPEDITED (15-DAY)		CA	US-FRI-1000043280	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrial septal defect	LEXAPRO	S	TRANSPLACENTAL			FOREST
	CELEXA	S				FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Mar-2013	9163969	EXPEDITED (15-DAY)		CA	US-FRI-1000043291	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cleft lip	LEXAPRO	S				FOREST
Cleft palate	CELEXA	S				FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Mar-2013	8697780	EXPEDITED (15-DAY)		OT	US-ASTRAZENECA-2012SE 47720	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Procedural complication	NEXIUM	S	ORAL			
Abasia	LEXAPRO	S	ORAL			
Abdominal pain upper	PROTONIX	S	UNKNOWN			
Anxiety						
Aphagia						
Drug dose omission						
Intentional drug misuse						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Mar-2013	9164792	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013085507	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nephrolithiasis	Lyrica	S		UNK		PFIZER
Musculoskeletal pain	GABAPENTIN	S		UNK		PFIZER
Depression	TOPAMAX	S	ORAL	100 mg, 1x/day (50mg, 2 in 1 day)		
Neoplasm	TOPAMAX	S				
Abnormal loss of weight	LEXAPRO	S		UNK		
Memory impairment	SYNTHROID	C		175 ug, in 1 day		
Alopecia						
Hair texture abnormal						
Influenza like illness						
Migraine						
Nausea						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Mar-2013	9166612	EXPEDITED (15-DAY)		CA	US-FRI-1000043307	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypoplastic right heart syndrome	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Mar-2013	9166668	EXPEDITED (15-DAY)		CA	US-FRI-1000043318	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fallot's tetralogy	LEXAPRO	S	TRANSPLACENTAL			FOREST
Right aortic arch	CELEXA	S	TRANSPLACENTAL			FOREST
Congenital anomaly						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Mar-2013	9166696	EXPEDITED (15-DAY)		CA,OT	US-FRI-1000043320	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Heart disease congenital	LEXAPRO	S	TRANSPLACENTAL			FOREST
Atrial septal defect						
Congenital aortic dilatation						
Transposition of the great vessels						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Mar-2013	8990870	EXPEDITED (15-DAY)		HO	JP-009507513-1212JPN 011109	27 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fall	REMERON	S	ORAL	0.5 DF, qd		MERCK
Fracture	REMERON	S	ORAL	1 DF, qd		MERCK
	LEXAPRO	S	ORAL	10 mg, qd		
	SOLANAX	S	ORAL	1.2 mg, qd		
	LOXONIN	S	ORAL	60 mg, qd		
	MUCOSTA	S	ORAL	300 mg, qd		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Mar-2013	9024924	EXPEDITED (15-DAY)		HO,OT	US-MERCK-1001USA00361		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal behaviour	RALTEGRAVIR POTASSIUM	S	ORAL	400 mg, bid		MERCK
Abdominal pain	RALTEGRAVIR POTASSIUM	S	ORAL	400 mg, bid		MERCK
Depression	RALTEGRAVIR POTASSIUM	S	ORAL	400 mg, bid		MERCK
Abdominal pain	DARUNAVIR	C	ORAL	600 mg, bid		
Suicidal ideation	DARUNAVIR	C	ORAL	UNK UNK, bid		
Gastritis	RITONAVIR	C	ORAL	100 mg, bid		
	RITONAVIR	C	ORAL	UNK UNK, bid		
	ETRAVIRINE	C	ORAL	200 mg, bid		
	BACTRIM DS	C	ORAL	On Monday, Tuesday and Wednesday		
	MELATONIN	C	ORAL			
	LEXAPRO	S	ORAL	5 mg, qd		
	LEXAPRO	S	ORAL	10 mg, qd		
	EPZICOM	S	ORAL	600/300		
	EPZICOM	S	ORAL	600/300		
	DEPO-PROVERA	C	INTRAMUSCULAR	UNK UNK, QM3		
	ZOLOFT	C	ORAL	UNK UNK, qd		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Mar-2013	9171973	EXPEDITED (15-DAY)		CA	US-FRI-1000043480	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Craniosynostosis	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Mar-2013	9182112	DIRECT		DS,OT		59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	LEXAPRO	S	ORAL			
Anxiety						
Aphagia						
Drug ineffective						
Impaired work ability						
Insomnia						
Irritability						
Loss of employment						
Obsessive-compulsive disorder						
Product substitution issue						
Tachyphrenia						
Weight decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Mar-2013	9182787	EXPEDITED (15-DAY)		OT	US-FRI-1000043618		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	LEXAPRO	S				FOREST
Drug hypersensitivity	CYMBALTA	S				
Anger						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Mar-2013	9191296	EXPEDITED (15-DAY)		OT	PHHY2013BR028434		Male	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Post-traumatic stress disorder	PAMELOR	S				
Sedation	CLONAZEPAM	S				NOVARTIS
Panic disorder	DIAZEPAM	S				
Depression	RIVOTRIL	S				
Decreased interest	BROMAZEPAM	S				
Abnormal behaviour	PAROXETINE	S				
	AMITRIPTYLINE	S				
	PRISTIQ	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Mar-2013	8445397	EXPEDITED (15-DAY)		HO	JP-FRI-1000028406	59 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Liver disorder	LEXAPRO	S	ORAL	10 mg		FOREST
Condition aggravated	LEXAPRO	S	ORAL	20 mg		FOREST
	LEXAPRO	S	ORAL	10 mg		FOREST
	RISPERDAL	S	ORAL	1 ml		
	RISPERDAL	S	ORAL	0.5 ml		
	RISPERDAL	S	ORAL	1.5 ml		
	RISPERDAL	S	ORAL	2 ml		
	JZOLOFT	C				
	MAGMITT	C	ORAL	1980 mg		
	SENNOSIDE	C	ORAL	24 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Mar-2013	9194353	EXPEDITED (15-DAY)		OT	US-RB-051453-13	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Foetal exposure during pregnancy	Suboxone tablet	S	TRANSPLACENTAL			RECKITT BENCKISER
Premature baby	Clonazepam	S	TRANSPLACENTAL	Dosing details unknown, dosing frequency: daily		
	Lexapro	S	TRANSPLACENTAL	Dosing details unknown, dosing frequency: daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Mar-2013	9199691	DIRECT	Y	DS,RI		52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Irritability	LEXAPRO	S	ORAL			
	ZOLOFT	C				
Social avoidant behaviour						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Mar-2013	9199695	DIRECT	Y				Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tremor	LEXAPRO	S	ORAL	oral		
Anxiety						
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Mar-2013	9055019	EXPEDITED (15-DAY)		OT	IE-FRI-1000042406	25 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Lethargy	LEXAPRO	S	ORAL	10 mg		FOREST
Bruxism	LEXAPRO	S	ORAL	5 mg		FOREST
Sleep disorder	CILEST	C	ORAL			
Fatigue	XANAX	C				
Confusional state						
Hyperhidrosis						
Memory impairment						
Myalgia						
Seizure like phenomena						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Mar-2013	9197865	EXPEDITED (15-DAY)		DE	US-FRI-1000043842	50 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Death	LEXAPRO	S				FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Mar-2013	9199752	DIRECT	Y	OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	LEXAPRO	S	ORAL			
Depression						
Irritability						
Product substitution issue						
Therapeutic response decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Mar-2013	9171554	EXPEDITED (15-DAY)		OT	JP-FRI-1000025967	60 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Neuroleptic malignant syndrome	LEXAPRO	S	ORAL	10 mg		FOREST
Neurogenic bladder	SEROQUEL	C	ORAL	150		
	BLOPRESS	C	ORAL	8 mg		
	THYRADIN	C	ORAL			
	HEBERNA	C	ORAL	75 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Mar-2013	9202332	DIRECT		OT		84 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Breast cancer	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2013	9207066	EXPEDITED (15-DAY)		OT	PHEH2013US007262		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicide attempt	TRILEPTAL	S		UNK UKN, UNK		NOVARTIS
Myocardial infarction	CONCERTA	S		UNK UKN, UNK		
Atrial fibrillation	EFFEXOR	S		UNK UKN, UNK		
Nasopharyngitis	LEXAPRO	S		UNK UKN, UNK		
Panic attack	AMBIEN	S		UNK UKN, UNK		
Disability	LITHIUM	S		UNK UKN, UNK		
	ATIVAN	S		UNK UKN, UNK		
	DEPAKOTE	S		UNK UKN, UNK		
	WELLBUTRIN	S		UNK UKN, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2013	9208266	EXPEDITED (15-DAY)		CA,OT	US-FRI-1000043878		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Talipes	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2013	9208293	EXPEDITED (15-DAY)		CA	US-FRI-1000043880	< 1 DAY	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diaphragmatic hernia	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Apr-2013	9210854	EXPEDITED (15-DAY)		DS,OT	US-FRI-1000043890		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrial fibrillation	LEXAPRO	S				FOREST
Myocardial infarction	EFFEXOR	S				
Nasopharyngitis	WELLBUTRIN	S		600 mg		
Self injurious behaviour	CONCERTA	S				
Unevaluable event	ATIVAN	S				
Unevaluable event	DEPAKOTE	S				
Unevaluable event	TRILEPTAL	S				
Unevaluable event	AMBIEN	S				
Unevaluable event	LITHIUM	S				
Panic attack						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Apr-2013	8495002	NON-EXPEDITED			US-PFIZER INC-2012084147	76 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	Xanax XR	S		2 mg, 1x/day		PFIZER
Anxiety	Zoloft	S		UNK		PFIZER
Nervousness	LEXAPRO	S		UNK		
Nausea	PROZAC	S		UNK		
Insomnia	TENORMIN	C		25 mg, daily		
Decreased appetite	CAPTOPRIL	C		25 mg, 2x/day		
Panic attack	GLYBURIDE	C		1.25 mg, daily		
Anxiety						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Apr-2013	9214237	EXPEDITED (15-DAY)		CA	US-FRI-1000044051		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Spina bifida occulta	LEXAPRO	S	TRANSPLACENTAL			FOREST
Arnold-Chiari malformation						
Conus medullaris syndrome						
Lipoma						
Spinal disorder						
Spine malformation						
Syringomyelia						
Tethered cord syndrome						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Apr-2013	9219322	DIRECT		DE		33 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Completed suicide	KLONOPIN	S				ROCHE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Apr-2013	8260806	EXPEDITED (15-DAY)		HO,CA,OT	US-JNJFOC-20111107265		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Motor developmental delay	TOPAMAX	S	TRANSPLACENTAL			
Cleft palate	PARACETAMOL	S	TRANSPLACENTAL			
Conductive deafness	PARACETAMOL	S	TRANSPLACENTAL			
Jaundice neonatal	LEXAPRO	S	TRANSPLACENTAL			
Speech disorder	LEVOTHYROXINE	S	TRANSPLACENTAL			
Feeding disorder	VICODIN	S	TRANSPLACENTAL			
Eustachian tube dysfunction	SUBOXONE	S	TRANSPLACENTAL			
Otitis media chronic	PRENATAL VITAMINS	S	TRANSPLACENTAL			
Weight decreased	OPIOIDS NOS	S	TRANSPLACENTAL			
Apnoea neonatal	SUBUTEX	S	TRANSPLACENTAL			
Bradycardia						
Fistula						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Apr-2013	9222505	EXPEDITED (15-DAY)		HO,DS,OT	US-SANOFI-AVENTIS-2013SA035501	38 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrial fibrillation	AMBIEN	S				
Myocardial infarction	EFFEXOR	S				
Legal problem	WELLBUTRIN	S				
Economic problem	CONCERTA	S				
Adverse event	ATIVAN	S				
Panic attack	DEPAKOTE	S				
Suicide attempt	TRILEPTAL	S				
Nasopharyngitis	LEXAPRO	S				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Apr-2013	9135109	NON-EXPEDITED			US-PFIZER INC-2013075067	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Somnolence	Lyrica	S	ORAL	50 mg, 2x/day		PFIZER
Headache	Lyrica	S				PFIZER
Drug ineffective	CAFFEINE	S		UNK		
	LEXAPRO	S		UNK		
	LANTUS	C		35 IU, daily at night		
	NOVOLOG	C		9 IU, after each meal		
	DEPAKOTE	C		UNK		
	HYDROXYZINE	C		UNK		
	HYDROXYZINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Apr-2013	9178217	EXPEDITED (15-DAY)		OT	US-RB-022557-11		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Panic attack	Subutex	S	UNKNOWN			RECKITT BENCKISER
Fatigue	Lexapro	S	UNKNOWN	Before bed time		
Hot flush	Nicotine	S	INHALATION	Smoking throughout pregnancy		
Thirst	PRENATAL VITAMINS	C	UNKNOWN	Dosing details unknown		
Dehydration						
Exposure during pregnancy						
Labour pain						
Premature delivery						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Apr-2013	9224559	EXPEDITED (15-DAY)		HO,DS,OT	US-JNJFOC-20130401623		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Disability	CONCERTA	S	ORAL			
Hospitalisation	WELLBUTRIN	S	UNKNOWN			
Atrial fibrillation	EFFEXOR	S	UNKNOWN			
Myocardial infarction	LEXAPRO	S	UNKNOWN			
Suicide attempt	LITHIUM	S	UNKNOWN			
Panic attack	ATIVAN	S	UNKNOWN			
Imprisonment	AMBIEN	S	UNKNOWN			
Nasopharyngitis	DEPAKOTE	S	UNKNOWN			
	TRILEPTAL	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Apr-2013	9226377	EXPEDITED (15-DAY)		CA	US-FRI-1000044105	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fallot's tetralogy	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Apr-2013	9226379	EXPEDITED (15-DAY)		CA	US-FRI-1000044107	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Talipes	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						
Patent ductus arteriosus						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Apr-2013	9227653	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-18753988		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mania	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Apr-2013	9229864	DIRECT	Y			57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Apr-2013	9158600	EXPEDITED (15-DAY)		OT	US-FRI-1000043193		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Breast cancer	LEXAPRO	S	ORAL	10 mg		FOREST
Depressed mood	LEXAPRO	S	ORAL	7.5 mg		FOREST
Crying	LEXAPRO	S	ORAL	5 mg		FOREST
Impatience	LEXAPRO	S	ORAL	2.5 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Apr-2013	9049613	EXPEDITED (15-DAY)		LT	JP-FRI-1000042415		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ventricular fibrillation	LEXAPRO	S	ORAL	10 mg		FOREST
	ETICALM	C	ORAL	0.5 mg		
	FLUNITRAZEPAM	C	ORAL	1 mg		
	SEDIEL	C	ORAL	10 mg		
	IRBETAN	C	ORAL			
	ALLERMIST	C	NASAL			
	HALCION	C	ORAL			
	GOODMIN	C	ORAL			
	TSUMURA	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Apr-2013	9236657	EXPEDITED (15-DAY)		CA	US-FRI-1000044385	< 1 DAY	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Talipes	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Apr-2013	9239278	EXPEDITED (15-DAY)		CA	US-FRI-1000044387	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Talipes	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Apr-2013	9240681	EXPEDITED (15-DAY)		CA	US-FRI-1000044389		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Oesophageal atresia Congenital anomaly	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Apr-2013	9240943	DIRECT	Y			11 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Product substitution issue	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2013	9104870	EXPEDITED (15-DAY)		DE,HO,OT	US-JNJFOC-20130206776		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug interaction	NUCYNTA ER	S	ORAL	100 mg- 3 tablets -twice a day		
Death	NUCYNTA ER	S	ORAL	twice daily		
Malignant neoplasm progression	NUCYNTA	S	ORAL	50 mg, 3 tablets every 4-6 hours as needed		
Depression	LEXAPRO	S	UNKNOWN	once daily		
Hallucination	OMEPRAZOLE	C	UNKNOWN	once a day		
Overdose	OXAZEPAM	C	UNKNOWN	once a day		
Drug ineffective	MAGIC MOUTHWASH	C	UNKNOWN	unspecified -tea spoon- every 4 hours as needed		
Failure to thrive	MAGNESIUM LACTATE	C	UNKNOWN	unspecified -tea spoon- every 4 hours as needed		
Confusional state						
Constipation						
Pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2013	9243070	EXPEDITED (15-DAY)		CA	US-FRI-1000044432	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pulmonary valve stenosis congenital	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2013	9247772	DIRECT					Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal pain	LEXAPRO	S	ORAL	10 MG 1/2 8 DAY PO		FOREST
Abdominal pain						
Activities of daily living impaired						
Diarrhoea						
Discomfort						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Apr-2013	9253944	DIRECT		DS		56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Parkinsonism	LEXAPRO	S	ORAL	20 mg. once daily po		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Apr-2013	8261077	EXPEDITED (15-DAY)		CA	US-JNJFOC-20111107543		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypospadias	TOPAMAX	S	TRANSPLACENTAL			
Growth retardation	TOPAMAX	S	TRANSPLACENTAL			
	LEXAPRO	S	TRANSPLACENTAL			
	ZOFRAN	S	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Apr-2013	9249551	EXPEDITED (15-DAY)		HO	AU-FRI-1000044541	44 YR	Male	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pleural effusion	LEXAPRO	S	ORAL	20 mg		FOREST
	SOMAC	S		20 mg		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Apr-2013	8330966	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-A0960414A	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Disability	Lamictal	S	ORAL	300MG Unknown		GLAXOSMITHKLINE
Abortion spontaneous	LAMOTRIGINE	S	ORAL	300MG Unknown		TEVA
Prescribed overdose	Microgestin	S	UNKNOWN			
Depression	Geodon	S	UNKNOWN			
Bedridden	Wellbutrin	S	ORAL			GLAXOSMITHKLINE
Hypersomnia	Effexor	S	UNKNOWN			GLAXOSMITHKLINE
Activities of daily living impaired	LEXAPRO	S	UNKNOWN			
Disturbance in attention	Contraceptive	S				
Stress	LIPITOR	C	ORAL			GLAXOSMITHKLINE
Exposure during pregnancy	Trileptal	C				
Drug level decreased	NORTRIPTYLINE	C				
Depressed mood	Folplex	C				
Mood altered	PRENATAL VITAMINS	C				
Drug interaction	FISH OIL	C				GLAXOSMITHKLINE

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Apr-2013	9252933	EXPEDITED (15-DAY)		OT	US-FRI-S04-USA-08048-01	42 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Homicide	LEXAPRO	S	ORAL			FOREST
Hallucination, auditory	LEXAPRO	S				FOREST
Agitation						
Anxiety						
Feeling abnormal						
Irritability						
Nervousness						
Withdrawal syndrome						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Apr-2013	7685386	EXPEDITED (15-DAY)		HO	US-BAXTER-2010BH024940	72 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Haemoglobin decreased	LEXAPRO	S	ORAL			
	NAMENDA	C	ORAL			
	ALENDRONATE SODIUM	C	ORAL			
	ASPIRINE	C	ORAL			
	FOLIC ACID W/VITAMIN B12	C	ORAL			
	LOPERAMIDE HYDROCHLORIDE	C	ORAL			
	CALCIUM W/VITAMIN D NOS	C	ORAL			
	EXELON	C	TRANSDERMAL			
	GAMMAGARD LIQUID	S	INTRAVENOUS	200 mg/ml body weight		
	GAMMAGARD LIQUID	S	INTRAVENOUS	200 mg/ml body weight		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Apr-2013	9262741	EXPEDITED (15-DAY)		HO	SYM-2013-03023	38 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Apr-2013	9261943	EXPEDITED (15-DAY)		CA	US-FRI-1000044723	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Craniosynostosis	LEXAPRO	S	TRANSPLACENTAL			FOREST
Anxiety						
Attention deficit/hyperactivity disorder						
Autism spectrum disorder						
Depression						
Expressive language disorder						
Headache						
Nausea						
Schizophrenia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Apr-2013	9248813	EXPEDITED (15-DAY)		OT	US-FRI-1000044644	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chest pain	LEXAPRO	S	ORAL	20 mg		FOREST
Bronchitis	OPC-34712	S	ORAL			
Hypertension	OPC-34712	S	ORAL	1 mg		
	LISINOPRIL	C	ORAL	20 mg		
	COREG	C	ORAL	6.25 mg		
	ACETAMINOPHEN	C		500 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Apr-2013	9264295	EXPEDITED (15-DAY)		CA	US-FRI-1000044725	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cleft palate	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-May-2013	9163993	EXPEDITED (15-DAY)		LT	JP-FRI-1000043367	47 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Altered state of consciousness	LEXAPRO	S	ORAL	10 mg		FOREST
	AMOXAN	C	ORAL	100 mg		
	TOFRANIL	C	ORAL	25 mg		
	TOFRANIL	C	ORAL	150 mg		
	TETRAMIDE	C	ORAL	20 mg		
	TRYPTANOL	C	ORAL	10 mg		
	LITHIUM CARBONATE	C	ORAL	100 mg		
	DOGMATYL	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-May-2013	9274819	DIRECT					Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	LEXAPRO	S				
Depressed mood						
Disease recurrence						
Drug ineffective						
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-May-2013	9275390	DIRECT		HO,LT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chest pain	LEXAPRO	S			1.5 YR	
Drug withdrawal syndrome						
Headache						
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-May-2013	9276695	EXPEDITED (15-DAY)		OT	SYM-2013-03220	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Impaired work ability	WELLBUTRIN (BUPROPION HYDROCHLORIDE) (BUPROPION HYDROCHLORIDE)	S	ORAL			
Abortion spontaneous	EFFEXOR (VENLAFAXINE HYDROCHLORIDE) UNKNOWN	S				
Depression	MICROGESTIN	S				
Hypersomnia	ZIPRASIDONE HCL	S				
Activities of daily living impaired	LEXAPRO	S				
Disturbance in attention	CONTRACEPTIVES	S				
Drug level decreased	ATORVASTATIN CALCIUM (ATORVASTATIN CALCIUM) (ATORVASTATIN CALCIUM)	C				
Pregnancy	OXCARBAZEPINE (OXCARBAZEPINE) (OXCARBAZEPINE)	C				
Product substitution issue	NORTRIPTYLINE (NORTRIPTYLINE) (NORTRIPTYLINE)	C				
Mood altered	FOLPLEX (HEPAGRISEVIT FORTE-N /01079901/) (PYRIDOXINE HYDROCHLORIDE, FOLIC ACID, CYANOCOBALAMIN)	C				
	PRENATAL VITAMINS (ASCORBIC ACID W/BIOTIN/MINERALS NOS/ NICOTINIC) (ASCORBIC ACID, BIOTIN, TOCOPHEROL, NICOTINIC ACID, RETINOL, MINERALS NOS, VITAMIN B NOS, VITAMIN D NOS)	C				
	FISH OIL (FISH OIL) (FISH OIL)	C				
Drug ineffective						
Drug interaction						
Pregnancy of unknown location						
Stress						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-May-2013	9268603	EXPEDITED (15-DAY)		CA	US-FRI-1000044727		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Talipes	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-May-2013	9275636	DIRECT		DS		53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Major depression	LEXAPRO	S	ORAL	5 milligrams once daily po		
Adrenocortical insufficiency acute						
Anxiety						
Decreased appetite						
Dry mouth						
Fear						
Flat affect						
Headache						
Insomnia						
Mood altered						
Muscle twitching						
Palpitations						
Panic attack						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-May-2013	9173341	EXPEDITED (15-DAY)		HO,CA,OT	US-JNJFOC-20130310413		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Choanal atresia	TOPAMAX	S	TRANSPLACENTAL			
Atrial septal defect	FOCALIN XR	S	TRANSPLACENTAL			
Heart valve incompetence	METOCLOPRAMIDE	S	TRANSPLACENTAL			
Nasal septum deviation	CLONAZEPAM	S	TRANSPLACENTAL			
Audiogram abnormal	LEXAPRO	S	TRANSPLACENTAL			
Deformity	KLONOPIN	S	TRANSPLACENTAL			
Emotional distress						
Pain						
Social avoidant behaviour						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-May-2013	9247366	EXPEDITED (15-DAY)		OT	US-JNJFOC-20130310412		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Emotional disorder	TOPAMAX	S	ORAL			
Exposure during pregnancy	FOCALIN XR	S	ORAL			
	FOCALIN XR	S	ORAL			
	METOCLOPRAMIDE	S	UNKNOWN			
	CLONAZEPAM	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	KLONOPIN	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-May-2013	9277410	DIRECT		OT		22 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Product substitution issue	LEXAPRO	S				
Drug withdrawal syndrome						
Product formulation issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-May-2013	9194232	EXPEDITED (15-DAY)		LT	JP-FRI-1000043785	17 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Activation syndrome	LEXAPRO	S	ORAL	10 mg		FOREST
Off label use	LEXAPRO	S	ORAL	20 mg		FOREST
	LEXAPRO	S	ORAL	10 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-May-2013	9249737	EXPEDITED (15-DAY)		OT	JP-FRI-1000044538	71 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	LEXAPRO	S	ORAL	10 mg		FOREST
	SELENICA-R	C	ORAL	400 mg		
	LIPITOR	C	ORAL	10 mg		
	THYRADIN S	C	ORAL	50 mg		
	SYMBICORT	C				
	MOSAPRIDE	C	ORAL	15 mg		
	LAC-B	C	ORAL	30 mg		
	MAGLAX	C	ORAL	990 mg		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-May-2013	9255219	EXPEDITED (15-DAY)		HO	US-JNJFOC-20130310450		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Premature labour	TOPAMAX	S	ORAL			
Exposure during pregnancy	MIRALAX	S	UNKNOWN			
Emotional disorder	DULCOLAX	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	REGLAN	S	UNKNOWN			
	ZOFRAN	S	UNKNOWN			
	ZOFRAN	S	UNKNOWN			
	METHADONE	S	UNKNOWN			
	PERCOCET	S	UNKNOWN			
	LORTAB	S	UNKNOWN			
	CYMBALTA	S	UNKNOWN			
	STADOL	S	UNKNOWN			
	DILAUDID	S	UNKNOWN			
	NEURONTIN	S	UNKNOWN			
	PROTONIX	S	UNKNOWN			
	BENTYL	S	UNKNOWN			
	PRENATAL VITAMINS	C	UNKNOWN			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-May-2013	9276034	NON-EXPEDITED		OT	US-PFIZER INC-2013139078		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Weight increased	Zoloft	S	ORAL	100 mg, 1 in 1 D		PFIZER
Gait disturbance	LEXAPRO	S	ORAL	10 mg, 1 in 1 D		
Oedema peripheral	AMITRIPTYLINE	S	ORAL	25 mg, 1 in 1 D		
Increased appetite	WARFARIN	C	ORAL	8 mg, Tu, Wed, Fri, Sat, Sun, 1 in 1 D		
Asthenia						
Glucose tolerance impaired						
Muscle spasms						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-May-2013	9277906	EXPEDITED (15-DAY)		HO	PHEH2013US010017	17 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Adverse reaction	TRILEPTAL	S				NOVARTIS
Fatigue	CONCERTA	S		UNK UKN, UNK		
Drug ineffective	ABILIFY	S		UNK UKN, UNK		
Feeling abnormal	ABILIFY	S		UNK UKN, UNK		
Crying	LEXAPRO	S		UNK UKN, UNK		
	SAPHRIS	S		UNK UKN, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-May-2013	9282197	DIRECT		OT		15 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO	S	ORAL			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-May-2013	9281323	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-18862946		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mania	ABILIFY	S		Started on 2 mg		
Pressure of speech	LEXAPRO	S				
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-May-2013	9285628	DIRECT	Y	OT		33 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Feeling abnormal	LEXAPRO	S	ORAL			
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-May-2013	9285538	NON-EXPEDITED			US-PFIZER INC-2013145521	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Neurontin	S		UNK		PFIZER
	Zoloft	S		UNK		PFIZER
	Effexor	S		UNK		PFIZER
	CODEINE	S		UNK		
	CYMBALTA	S		UNK		
	TALWIN	S		UNK		
	PROVIGIL	S		UNK		
	Opana	S		UNK		
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-May-2013	9285687	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013143980		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Urinary tract infection	AMLODIPINE BESILATE	S		UNK		PFIZER
Drug interaction	LEVOTHYROXINE	S		50 ug, five days a week		
Malaise	LEVOTHYROXINE	S		75 ug, two days in weekend		
Breath odour	LEXAPRO	S		UNK		
Skin odour abnormal	SYNTHROID	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-May-2013	9286427	EXPEDITED (15-DAY)		CA	US-FRI-1000045016	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrial septal defect	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-May-2013	9290753	EXPEDITED (15-DAY)		OT	JP-FRI-1000044717	88 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypotension	LEXAPRO	S	ORAL	10 mg		FOREST
Drug interaction	CLOTIAZEPAM	S	ORAL	5 mg		
	BAYASPIRIN	C	ORAL	100 mg		
	IRBETAN	C	ORAL	50 mg		
	ARTIST	C	ORAL	2.5 mg		
	TOWARAT-CR	C	ORAL	20 mg		
	MEQUITOLIDE	C	ORAL			
	VASOLATOR	C	OTHER	27 mg		
	CRESTOR	C	ORAL			
	GLACTIV	C	ORAL	50 mg		
	CELECOX	C	ORAL	200 mg		
	ITOPRIDE HYDROCHLORIDE	C	ORAL	150 mg		
	POCEVIN	C	INTRAMUSCULAR			
	NITROGLYCERIN	C	SUBLINGUAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-May-2013	9291118	EXPEDITED (15-DAY)		OT	US-NICOBRDEVP-2013-08103		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Disability	MICROGESTIN	S	ORAL	UNK		WATSON
Abortion spontaneous	LAMOTRIGINE (WATSON LABORATORIES)	S	ORAL	300 mg, UNK		WATSON
Overdose	Venlafaxine Hydrochloride (Unknown)	S	UNKNOWN	UNK		
Depression	LAMICTAL	S	ORAL	300 mg, UNK		
Bedridden	ZIPRASIDONE	S	UNKNOWN	UNK		
Hypersomnia	WELLBUTRIN	S	ORAL	UNK		
Decreased activity	LEXAPRO	S	UNKNOWN	UNK		
Disturbance in attention	ATORVASTATIN CALCIUM	C	UNKNOWN	UNK		
Maternal exposure during pregnancy	OXCARBAZEPINE	C	UNKNOWN	UNK		
Drug level decreased	NORTRIPTYLINE	C	UNKNOWN	UNK		
Depressed mood	FOLPLEX	C	UNKNOWN	UNK		
Mood altered	PRENATAL VITAMINS / 01549301/	C	UNKNOWN	UNK		
Drug interaction	FISH OIL	C	UNKNOWN	UNK		
Activities of daily living impaired						
Impaired work ability						
Stress						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-May-2013	9197683	EXPEDITED (15-DAY)		OT	IE-FRI-1000043807	92 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tremor	LEXAPRO	S	ORAL	5 mg		FOREST
Head titubation	AMLODIPINE	C				
Dyskinesia	STATIN	C				
	PERSANTIN RETARD	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-May-2013	9292023	NON-EXPEDITED			US-PFIZER INC-2013150301	36 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Malaise	Lyrica	S		75 mg, UNK		PFIZER
Somnolence	LEXAPRO	S		UNK		
Middle insomnia	XANAX	C		UNK		
Nausea	ELAVIL	C		UNK		
	VICODIN	C		7.5mg/750mg		
	SKELAXIN	C		UNK		
	TRAMADOL	C		UNK		
	TRAMADOL	C				
	MOBIC	C		UNK		
	VITAMIN B12	C		1000mg once a week		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-May-2013	9241120	EXPEDITED (15-DAY)		LT,OT	JP-FRI-1000044481	80 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicide attempt	LEXAPRO	S	ORAL	10 mg		FOREST
Homicide	MEVAN	C	ORAL	10 mg		
	AMLODIPINE OD	C	ORAL	5 mg		
	DEPAS	C	ORAL	0.5 mg		
	REBAMIPIDE	C	ORAL	300 mg		
	NEUROTROPIN	C	ORAL	12 UT		
	RINGEREAZE	C	ORAL	60 mg		
	PA	C	ORAL	2 DF		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-May-2013	9269673	EXPEDITED (15-DAY)		HO	JP-FRI-1000044889	63 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anaphylactic reaction	LEXAPRO	S	ORAL	10 mg		FOREST
	LIMAS	S	ORAL	200 mg		
	AMOXAN	S	ORAL	150 mg		
	DIOVAN	C	ORAL			
	SOLANAX	C	ORAL			
	LENDEM	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-May-2013	9279030	EXPEDITED (15-DAY)		OT	US-FRI-1000044954		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	DALIRESP	S	ORAL	500 MCG		FOREST
Impulsive behaviour	PREDNISONE	S				
Coma	LEXAPRO	S				
	XANAX	S				
	MORPHINE	S				
	OXYCODONE	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-May-2013	9296708	NON-EXPEDITED		HO	JP-FRI-1000045247	61 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	LEXAPRO	S	ORAL	10 mg		FOREST
Dizziness						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-May-2013	9297658	DIRECT	Y	OT		37 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Imprisonment	RISPERIDONE	S				
Anxiety						
Dyspnoea						
Fear						
Incorrect dose administered						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-May-2013	9301632	DIRECT	Y	OT		33 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Feeling abnormal	LEXAPRO	S	ORAL			
Fear						
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-May-2013	8961684	EXPEDITED (15-DAY)		HO	JP-FRI-1000040992	41 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Torsade de pointes	LEXAPRO	S	ORAL	10 mg		FOREST
Ventricular fibrillation	LEXAPRO	S	ORAL	10 mg		FOREST
Apathy	TAKEPRON	S	ORAL	15 mg		
Drug interaction	LAMICTAL	C	ORAL	100 mg		
	LANDSEN	C	ORAL			
	RIVOTRIL	C	ORAL	0.5 mg		
	PLAVIX	C	ORAL	75 mg		
	BAYASPIRIN	C	ORAL	100 mg		
	CRESTOR	C	ORAL	2.5 mg		
	NICORANDIS	C	ORAL	15 mg		
	MAGNESIUM OXIDE	C	ORAL	1.5 Gram		
	SOLITA-T NO.1	C	INTRAVENOUS DRIP			
	HEPARIN SODIUM	C	INTRAVENOUS DRIP	12 KU		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-May-2013	9306271	EXPEDITED (15-DAY)		CA	US-FRI-1000045236	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Transposition of the great vessels	LEXAPRO	S	TRANSPLACENTAL			FOREST
Pulmonary artery stenosis congenital						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2013	9223204	EXPEDITED (15-DAY)		HO,OT	JP-009507513-1304JPN 002734	65 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fall	REMERON	S	ORAL	15 mg, qd		MERCK
Skull fracture	UNDEPRE	S	ORAL	25 mg, tid		
Extradural haematoma	CYMBALTA	S	ORAL	20 mg, bid		
Pneumocephalus	LEXAPRO	S	ORAL	10 mg, qd		
Pancytopenia	SULPIRIDE	C	ORAL	50 mg, tid		
Delirium						
White blood cell count decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2013	9307576	NON-EXPEDITED			US-PFIZER INC-2013154469	69 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug interaction	Viagra	S		50 mg, as needed		PFIZER
Drug ineffective	LEXAPRO	S		20 mg daily		
	WELLBUTRIN	S		150 mg, 2x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2013	9308189	EXPEDITED (15-DAY)		OT	US-TEVA-406772USA		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Urinary tract infection	LEVOTHYROXINE SODIUM FOR INJECTION,200 MCG/6 ML VIAL & 500 MCG/6 ML VI	S		50 mcg, five days a week and 75mcg for two days in weekend		TEVA
Drug interaction	LEVOXYL	S				
Breath odour	LEXAPRO	S				
Parosmia	AMLODIPINE	S				
Malaise						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-May-2013	9311586	NON-EXPEDITED			US-PFIZER INC-2013158678	79 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	LIPITOR	S		UNK		PFIZER
	LEXAPRO	S		UNK		
	PENICILLIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-May-2013	9315338	NON-EXPEDITED			US-PFIZER INC-2013163389	45 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Zoloft	S		UNK		PFIZER
	ABILIFY	S		UNK		
	LEXAPRO	S		UNK		
	LUNESTA	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-May-2013	9192603	NON-EXPEDITED			US-PFIZER INC-2013095165	33 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	Effexor XR	S		150 mg, daily		PFIZER
Abnormal sensation in eye	Effexor XR	S		75 mg, daily		PFIZER
Sensory disturbance	Effexor XR	S		37.5 mg, daily		PFIZER
Feeling abnormal	Effexor XR	S		UNK		PFIZER
Tinnitus	LEXAPRO	S		UNK		
Drug dose omission	TRAZODONE	C		UNK		
	VALACICLOVIR HYDROCHLORIDE	C		500 mg, daily		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-May-2013	9280791	EXPEDITED (15-DAY)		HO,OT	US-PFIZER INC-2013143519		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Complex regional pain syndrome	GABAPENTIN	S		UNK		PFIZER
Pain	Lyrica	S		UNK		PFIZER
Dyskinesia	CYMBALTA	S		UNK		
Concussion	LEXAPRO	S		UNK		
Activities of daily living impaired						
Aphagia						
Apparent death						
Bedridden						
Brain injury						
Cognitive disorder						
Contusion						
Diarrhoea						
Dyspnoea						
Feeling abnormal						
Injury						
Irritability						
Malaise						
Memory impairment						
Pain						
Periorbital contusion						
Swelling						
Upper limb fracture						
Vomiting						
Weight decreased						
Withdrawal syndrome						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-May-2013	9321085	DIRECT					Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Irritable bowel syndrome	LEXAPRO	S	ORAL	20mg daily by mouth		
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2013	9213902	EXPEDITED (15-DAY)		OT	IE-FRI-1000044030	30 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Withdrawal syndrome	LEXAPRO	S	ORAL	20 mg		FOREST
Abdominal discomfort	LEXAPRO	S	ORAL	15 mg		FOREST
Dizziness	LEXAPRO	S	ORAL	10 mg		FOREST
Visual field defect	LEXAPRO	S	ORAL	5 mg		FOREST
	LEXAPRO	S	ORAL	10 mg		FOREST
	LEXAPRO	S				FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2013	9213906	EXPEDITED (15-DAY)		OT	IE-FRI-1000044029		Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Withdrawal syndrome	LEXAPRO	S	ORAL			FOREST
Abdominal discomfort	LEXAPRO	S		10 mg		FOREST

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2013	9321389	EXPEDITED (15-DAY)		OT	US-FRI-1000045429		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	CELEXA	S				FOREST
Panic attack	LEXAPRO	S		10 mg		FOREST
Haematochezia	HUMIRA	S		40 mg		
Crohn's disease	LISINOPRIL	C		10/12.5mg		
	LISINOPRIL	C				
	CARTIA	C		180 mg		FOREST
	ASACOL	C		6 dosage forms		
	DIPHENHYDRAMINE	C		25 mg		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-May-2013	9321544	EXPEDITED (15-DAY)		HO,OT	US-FRI-1000045450		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Complex regional pain syndrome	LEXAPRO	S				FOREST
Concussion	LYRICA	S				
Upper limb fracture	CYMBALTA	S				
Pain	GABAPENTIN	S				
Apparent death						
Bedridden						
Contusion						
Decreased appetite						
Diarrhoea						
Drug withdrawal syndrome						
Dyskinesia						
Dysphagia						
Dyspnoea						
Fear of death						
Irritability						
Malaise						
Memory impairment						
Mental impairment						
Movement disorder						
Negative thoughts						
Periorbital contusion						
Post-traumatic pain						
Swelling						
Unevaluable event						
Vomiting						
Weight decreased						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Jun-2013	9323974	NON-EXPEDITED			US-PFIZER INC-2013166796	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	Pristiq	S		50 mg, daily		PFIZER
Back disorder	Pristiq	S		100 mg, daily		PFIZER
Fatigue	Effexor XR	S		UNK		PFIZER
Feeling abnormal	WELLBUTRIN	S		UNK		
Night sweats	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Jun-2013	9326557	DIRECT	Y	HO		30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pruritus	LEXAPRO	S				
Swelling face	ESCITALOPRAM	S				
Rash						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Jun-2013	9326190	EXPEDITED (15-DAY)		DE,CA	US-FRI-1000045583	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Persistent foetal circulation	LEXAPRO	S	TRANSPLACENTAL			FOREST
	LEXAPRO	S				FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Jun-2013	9327654	NON-EXPEDITED			US-PFIZER INC-2013167706	37 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Pristiq	S		UNK		PFIZER
	Flector	S		UNK		PFIZER
	MIRTAZAPINE	S		UNK		
	AMBIEN	S		UNK		
	CYMBALTA	S		UNK		
	LEXAPRO	S		UNK		
	WELLBUTRIN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jun-2013	8541791	EXPEDITED (15-DAY)		LT	JP-FRI-1000030140	41 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertriglyceridaemia	LEXAPRO	S	ORAL	20 mg		FOREST
	REFLEX	C	ORAL	15 mg		
	REFLEX	C		45 mg		
	GASMOTIN	C	ORAL	5 mg		
	ROHYPNOL	C	ORAL	2 mg		
	RESLIN	C	ORAL	200 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jun-2013	8806652	EXPEDITED (15-DAY)		DE,HO	US-BRISTOL-MYERS SQUIBB COMPANY-15274749	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sepsis	IPILIMUMAB	S	INTRAVENOUS	No of courses: 02		
Deep vein thrombosis	LEXAPRO	S				
Hyponatraemia	DIOVAN HCT	C				
	ENABLEX	C				
	FLOMAX	C				

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	ASPIRIN	C				
	COREG	C				
	LANOXIN	C				
	AMARYL	C				
	LASIX	C				
	ULTRAM	C				
	ZESTRIL	C				
	NEXIUM	C				
	K-DUR	C				
	LORTAB	C				
	OXY-IR	C				
	LIPITOR	C				
	LOSEC	C				
	GLYBURIDE	C				
	FIBERCON	C				
	COUMADIN	C				
	LEXAPRO	C				
	DURAGESIC	C				
	LORTAB	C				
	DIGOXIN	C				
	TRAMADOL	C		ER		
	CARVEDILOL	C				
	VALSARTAN + HCTZ	C				
	DARIFENACIN HYDROBROMIDE	C				
	TAMSULOSIN HCL	C				
	GLIMEPIRIDE	C				
	FUROSEMIDE	C				
	ESCITALOPRAM OXALATE	C				
	APAP	C		1DF=500 unit not given.		
	HYDROCODONE	C		1DF=1DF=7.5 unit not given.		

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	ATORVASTATIN CALCIUM	C				
	LISINOPRIL	C				
	OXYCODONE	C				
	POTASSIUM	C				
	WARFARIN SODIUM	C				
	ESOMEPRAZOLE MAGNESIUM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jun-2013	9310536	NON-EXPEDITED			US-PFIZER INC-2013158972	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Effexor	S		UNK		PFIZER
	Neurontin	S		UNK		PFIZER
	Vistaril	S		UNK		PFIZER
	DEMEROL	S		UNK		
	LEXAPRO	S		UNK		
	TEGRETOL	S		UNK		
	TOPAMAX	S		UNK		
	VALIUM	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jun-2013	9200249	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2013094901	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	ZIPRASIDONE HCL	S	ORAL	60 mg, 2x/day		PFIZER
	Lexapro	S		UNK		
	TRAZODONE	C	ORAL	150 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jun-2013	9341291	DIRECT					Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	ESCITALOPRAM	S				
Adverse event						
Product quality issue						
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jun-2013	9291364	EXPEDITED (15-DAY)		OT	US-FRI-1000045024	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Angina pectoris	LEXAPRO	S	ORAL	20 mg		FOREST
Depression	LEXAPRO	S	ORAL	20 mg		FOREST
Hypothyroidism	VIIBRYD	S	ORAL	10 mg		FOREST
Anger	VIIBRYD	S	ORAL	20 mg		FOREST
	COUMADIN	C				
	IBUPROFEN	C				
	LASIX	C				
	SYNTHROID	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jun-2013	9300530	EXPEDITED (15-DAY)		HO	JP-FRI-1000045210		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depressed level of consciousness	LEXAPRO	S	ORAL	Overdose: 5 tablets		FOREST
Peripheral coldness	DEPAKENE	S	ORAL	Overdose: 13 tablet of sodium valproate 200 mg		
Dysarthria	FLUNITRAZEPAM	S	ORAL	3 mg		
Toxicity to various agents	BIOFERMIN	C	ORAL	4 DF		
Overdose	PRIMPERAN	C	ORAL	10 mg		
	STOMACHICS AND DIGESTIVES	C	OTHER			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jun-2013	9348935	EXPEDITED (15-DAY)		OT	PL-FRI-1000045925		Male	POL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Immunosuppression	LEXAPRO	S	ORAL	10 mg		FOREST
Nasal inflammation	LEXAPRO	S	ORAL			
Myalgia						
Tendon pain						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Jun-2013	8586962	NON-EXPEDITED			US-ASTRAZENECA-2012SE31459	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Trismus	SEROQUEL	S	ORAL			
Hypothyroidism	SEROQUEL	S	ORAL			
Renal impairment	SEROQUEL	S	ORAL			
Hypertension	SEROQUEL	S	ORAL			
Somnolence	SEROQUEL	S	ORAL			
Fatigue	SEROQUEL	S	ORAL			
	METOPROLOL	S	UNKNOWN			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO	S	ORAL			
	LEXAPRO (LUPIN)	S	ORAL			
	DEPAKOTE	S	ORAL			
	DEPAKOTE	S	ORAL			
	DEPAKOTE	S	ORAL			
	DEPAKOTE	S	ORAL			
	DEPAKOTE	S	ORAL			
	DEPAKOTE	S	ORAL			
	SYNTHROID	C	ORAL			
	CLOMIPRAMINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Jun-2013	9351102	EXPEDITED (15-DAY)		CA	US-FRI-1000045842	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Talipes	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jun-2013	8584812	EXPEDITED (15-DAY)		DE	JP-FRI-1000030817		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Death	LEXAPRO	S	ORAL	10 mg		FOREST
Depression	MEDIPEACE	S	ORAL	1 mg		
	AMOBAN	S	ORAL	7.5 mg		
	MUCOSTA	C	ORAL	200 mg		
	GOODMIN	C	ORAL	0.25 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jun-2013	8610171	EXPEDITED (15-DAY)		LT	JP-FRI-1000031190	86 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Inappropriate antidiuretic hormone secretion	LEXAPRO	S	ORAL	10 mg		FOREST
	JZOLOFT	S	ORAL	50 mg		
	GASCON	C	ORAL	120 mg		
	DOGMATYL	C	ORAL	100 mg		
	TAKEPRON	C	ORAL	15 mg		
	PREDONINE	C	INTRAVENOUS	10 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jun-2013	9308346	EXPEDITED (15-DAY)		OT	US-FRI-1000045324		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gynaecomastia	LEXAPRO	S	ORAL	10 mg		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jun-2013	9321663	EXPEDITED (15-DAY)		HO	JP-FRI-1000045486		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rhabdomyolysis	LEXAPRO	S	ORAL	10 mg		FOREST
	THEODUR	S	ORAL			
	SEKINARIN	S	ORAL			
	ZYPREXA	C	ORAL	5 mg		
	CYMBALTA	C	ORAL	20 mg		
	REFLEX	C	ORAL	15 mg		
	LIMAS	C	ORAL	400 mg		
	DEPAKENE-R	C	ORAL	400 mg		
	HORIZON	C	ORAL	10 mg		
	WYPAX	C	ORAL	1 mg		
	AMLODIPINE	C	ORAL	10 mg		
	LIPITOR	C	ORAL	5 mg		
	FLUITRAN	C	ORAL	2 mg		
	LAMISIL	C	ORAL	125 mg		
	IMIDAPRIL HYDROCHLORIDE	C	ORAL	5 mg		
	CERNILTON	C	ORAL	6 DF		
	LANSOPRAZOLE	C	ORAL	15 mg		
	ADETPHOS	C	ORAL	300 mg		
	BETAHISTINE MESILATE	C	ORAL	36 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jun-2013	9360923	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	LEXAPRO	S	ORAL	Lexapro 10 mg daily oral	1 MTH	
Product quality issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jun-2013	9369884	EXPEDITED (15-DAY)		HO	JP-FRI-1000046217	31 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Altered state of consciousness	LEXAPRO	S		Overdose: 29 tablets		FOREST
Overdose	TRIAZOLAM	S		Overdose: 40 tablets		
	CLONAZEPAM	S		Overdose: 7 tablets		
	FLUNITRAZEPAM	S		Overdose: 61 tablets		
	BLONANSERIN	S		Overdose: unknown dose		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jun-2013	9370048	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013188156		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depression	Premarin	S		UNK, (0.45)		PFIZER
Nausea	Zoloft	S		UNK		PFIZER
Dry mouth	LEXAPRO	S		UNK		
Decreased appetite						
Fatigue						
Night sweats						
Urine output decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jun-2013	8830516	EXPEDITED (15-DAY)		DE,OT	JP-PFIZER INC-2012216483	52 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Breast cancer	Lyrica	S	ORAL	75 mg, 2x/day		PFIZER
Renal failure	Lyrica	S		75 mg, 1x/day		PFIZER
Device occlusion	Lyrica	S		25 mg, 1x/day		PFIZER
Myoclonus	LEXAPRO	S	ORAL	10 mg, 1x/day		
Somnolence	LEXAPRO	S	ORAL	10 mg, 1x/day		
Dizziness	FENTOS TAPE	S	TRANSDERMAL	6 mg, 1x/day		
Affect lability	TAKEPRON OD	C	ORAL	15 mg, 1x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jun-2013	9372509	EXPEDITED (15-DAY)		OT	JP-FRI-1000046209	78 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Granulocyte count decreased	LEXAPRO	S	ORAL	10 mg		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jun-2013	9372760	EXPEDITED (15-DAY)		DE,CA	US-FRI-1000046153	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anomalous pulmonary venous connection	LEXAPRO	S	TRANSPLACENTAL			FOREST
Atrial septal defect						
Coarctation of the aorta						
Congenital anomaly						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jul-2013	9286407	EXPEDITED (15-DAY)		OT	US-FRI-1000044974	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Premature baby	LEXAPRO	S	TRANSPLACENTAL			FOREST
Anxiety						
Attention deficit/hyperactivity disorder						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jul-2013	9376979	EXPEDITED (15-DAY)		HO	JP-FRI-1000046317	39 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depressed level of consciousness	LEXAPRO	S	ORAL	overdose 350 mg		FOREST
Mouth breathing	SOLANAX	S	ORAL	overdose 210 mg		
Overdose	DOGMATYL	S	ORAL	overdose 190 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jul-2013	9379508	EXPEDITED (15-DAY)		CA	US-FRI-1000046300		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Craniosynostosis	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jul-2013	9379530	EXPEDITED (15-DAY)		CA	US-FRI-1000046312	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Talipes	LEXAPRO	S	TRANSPLACENTAL			FOREST
Limb reduction defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jul-2013	9379573	EXPEDITED (15-DAY)		CA	US-FRI-1000046308		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Craniosynostosis	LEXAPRO	S	TRANSPLACENTAL			FOREST

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jul-2013	9384169	DIRECT		OT		64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	LEXAPRO	S	ORAL			
Dizziness	VICTOZA	C				
Hypertension						
Presyncope						
Vertigo						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Jul-2013	9247008	EXPEDITED (15-DAY)		HO	US-AMGEN-USASP2013024370	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Grand mal convulsion	Enbrel	S		50 mg, qwk		AMGEN
Drug interaction	Enbrel	S				AMGEN
Migraine	Enbrel	S				AMGEN
Arthralgia	TRAMADOL / 00599202/	S		UNK		
Injection site erythema	LEXAPRO	S		UNK		
Injection site pain						
Injection site swelling						
Injection site warmth						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2013	9322157	EXPEDITED (15-DAY)		HO	JP-FRI-1000045084		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Serotonin syndrome	LEXAPRO	S	ORAL	10 mg		FOREST
Drug interaction	METHISTA	S	ORAL	1500 mg		
	HUSCODE	S	ORAL	6 DF		
	CEFCAPENE PIVOXIL HYDROCHLORIDE HYDRATE	S	ORAL	3 DF		
	PRANLUKAST	S	ORAL	4 DF		
	BESASTAR SR	C	ORAL	400 mg		
	DEPAS	C	ORAL	3 mg		
	MINZAIN	C	ORAL	0.25 mg		
	AMLODIPINE OD	C	ORAL			
	CALONAL	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2013	9391815	NON-EXPEDITED		LT,OT	US-ASTRAZENECA-2013SE 51162		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicide attempt	SEROQUEL	S	ORAL			ZENECA
Adverse drug reaction	ZOLOFT	S				
	LEXAPRO	S				
	PAXIL	S				
	ABILIFY	S				
	EFFEXOR	S				
	LAMICTAL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jul-2013	9342442	EXPEDITED (15-DAY)		LT	JP-FRI-1000045785		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ventricular tachycardia	LEXAPRO	S	NASAL	10 mg		FOREST
Electrocardiogram QT prolonged	LEXAPRO	S	NASAL	10 mg		FOREST
Cardio-respiratory arrest	LEXAPRO	S	NASAL	20 mg		
Off label use	ARICEPT D	S	NASAL	2.5 mg		
	ARICEPT D	S	NASAL	5 mg		
	DAIKENCHUTO	C	ORAL			
	MAGMITT	C	ORAL			
	ZYPREXA	C		2.5 mg		
	ZYPREXA	C		5 mg		
	ZYPREXA	C		2.5 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jul-2013	8599926	EXPEDITED (15-DAY)		HO	JP-FRI-1000030944		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	LEXAPRO	S	ORAL	10 mg		FOREST
Hallucination	LANDSEN	C	ORAL	2 mg		
Paranoia	NIZATIDINE	C	ORAL	75 mg		
Epileptic psychosis						
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jul-2013	9397542	EXPEDITED (15-DAY)		CA,OT	US-PFIZER INC-2013202479		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal exposure during pregnancy	Zoloft	S	TRANSPLACENTAL	UNK		PFIZER
Hypoplastic left heart syndrome	SERTRALINE HCL	S	TRANSPLACENTAL	UNK		PFIZER
Congenital anomaly	LEXAPRO	S	TRANSPLACENTAL	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jul-2013	9400447	DIRECT				63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depression	LEXAPRO 10MG (GENERIC)	S	ORAL	Strength: 10mg Quantity: 90 (3 mo) Frequency: daily Orally	90 DAY	
Product substitution issue	SYNTHROID	C				
	KLONOPIN	C				
	RESTASIS	C				
	GABAPENTIN	C				
	COSAMINE DS	C				
	TYLENOL	C				
	MULTIVITAMIN	C				
	L LYSINE	C				
	VITAMIN D	C				
Crying						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2013	9400179	EXPEDITED (15-DAY)		DE,CA	US-FRI-1000046578	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypoplastic left heart syndrome	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						
Pulmonary hypertension						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jul-2013	9403260	EXPEDITED (15-DAY)		CA	US-FRI-1000046590		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hydrocephalus	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						
Exomphalos						
Patent ductus arteriosus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Jul-2013	9166364	EXPEDITED (15-DAY)		CA	US-JNJFOC-20111104297		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cleft lip and palate	TOPAMAX	S	TRANSPLACENTAL			
Dental alveolar anomaly	ZANTAC	S	TRANSPLACENTAL			
Dysarthria	KEPPRA	S	TRANSPLACENTAL			
Social avoidant behaviour	LEXAPRO	S	TRANSPLACENTAL			
	AZITHROMYCIN	S	TRANSPLACENTAL			
	SULPHACETAMIDE	S	TRANSPLACENTAL			
	PHENERGAN	S	TRANSPLACENTAL			
	ACEBUTOLOL	S	TRANSPLACENTAL			
	FERROUS SULFATE	C	TRANSPLACENTAL			
	FOLIC ACID	C	TRANSPLACENTAL			
	PRENATAL VITAMINS	C	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jul-2013	9407919	EXPEDITED (15-DAY)		OT	US-FRI-1000046701	32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rheumatoid arthritis	LEXAPRO	S				FOREST

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2013	9361465	EXPEDITED (15-DAY)		HO,OT	JP-FRI-1000043168		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Serotonin syndrome	LEXAPRO	S	ORAL	10 mg		FOREST
Treatment noncompliance	MEMARY	C	ORAL	5 mg		
Decubitus ulcer	MEMARY	C	ORAL	6 DF		
Poriomania	MEMARY	C	ORAL	10 mg		
Urinary incontinence	MEMARY	C	ORAL	5 mg		
Pneumonia aspiration	DESYREL	C	ORAL	50 mg		
Apathy	DESYREL	C	ORAL	6 DF		
	DESYREL	C	ORAL	25 mg		
	REZALTAS	C	ORAL			
	SELUMITO	C	ORAL			
	LOXOPROFEN	C				
	ALESION	C	ORAL			
	OINTMENT BASES	C	TOPICAL			
	VESICARE	C	ORAL			
	DEPAS	C	ORAL			
	AMOBAN	C	ORAL			
	LENDORMIN	C	ORAL			

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2013	9409347	NON-EXPEDITED			US-PFIZER INC-2013211073	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Zoloft	S		UNK		PFIZER
	NEFAZODONE	S		UNK		
	LEXAPRO	S		UNK		
	ALLEGRA	S		UNK		
	HYDROCODONE BITARTRATE	S		UNK		
	MELOXICAM	S		UNK		
	CLARITHROMYCIN	S		UNK		
	ACETAMINOPHEN	S		UNK		
	PENICILLIN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jul-2013	9414847	EXPEDITED (15-DAY)		CA	US-FRI-1000046814	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebral palsy	LEXAPRO	S				FOREST
Microcephaly						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jul-2013	9416347	DIRECT		OT		59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug withdrawal syndrome	LEXAPRO	S	ORAL	1, daily, po		TEVA
Anxiety						
Decreased appetite						
Dyskinesia						
Feeling abnormal						
Gastrointestinal disorder						
Hypertension						
Nervousness						
Product substitution issue						
Shock						
Therapeutic response unexpected with drug substitution						
Thinking abnormal						
Weight decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jul-2013	9420531	NON-EXPEDITED			US-ABBOTT-13P-163-1098937-00		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Malaise	SYNTHROID	S				
Breath odour	AMLODIPINE	S				
Skin odour abnormal	LEXAPRO FILM-COATED TABLETS	S				
Drug interaction	LEVOTHYROXINE	S		50MCG: 5 DAYS A WEEK AND75MCG: 2 DAYS A WEEK		
Urinary tract infection	LEVOXYL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jul-2013	9421768	EXPEDITED (15-DAY)		DE	AU-ASTRAZENECA-2013SE56043	152 DAY	Unknown	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Foetal exposure during pregnancy	SEROQUEL	S	TRANSPLACENTAL			ZENECA
Microencephaly	LEXAPRO	S	TRANSPLACENTAL			
Escherichia sepsis						
Necrotising enterocolitis neonatal						
Peritoneal haemorrhage						
Peritonitis						
Premature delivery						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jul-2013	9431468	EXPEDITED (15-DAY)		CA	US-FRI-1000046970	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fallot's tetralogy	CELEXA	S	TRANSPLACENTAL			FOREST
Atrial septal defect	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Jul-2013	9432098	NON-EXPEDITED			US-PFIZER INC-2013221390	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Effexor	S		UNK		PFIZER
	ERYTHROMYCIN	S		UNK		
	VICODIN	S		UNK		
	BIAXIN	S		UNK		
	LEXAPRO	S		UNK		
	PROZAC	S		UNK		
	SYNTHROID	S		UNK		
	PAXIL	S		UNK		
	BACTRIM	S		UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Aug-2013	9437544	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2013S1016531	40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Exposure during pregnancy	AMNESTEEM CAPSULES	S				MYLAN
	CLARAVIS	S				MYLAN
	LATISSE	S				
	LEXAPRO	S				
	ORAL CONTRACEPTIVE NOS	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Aug-2013	9442189	DIRECT		LT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	LEXAPRO	S	ORAL		1 MTH	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Aug-2013	9444176	DIRECT	Y	OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	LEXAPRO	S	ORAL	20mg daily po		
	ZYPREXA	C				
	TRAZADONE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Aug-2013	9347064	EXPEDITED (15-DAY)		HO	JP-GLAXOSMITHKLINE-B0872038A		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mania	Lamictal	S	ORAL	50MG Per day		GLAXOSMITHKLINE
Affect lability	Lamictal	S	ORAL			GLAXOSMITHKLINE
Logorrhoea	Lamictal	S	ORAL	50MG Twice per day		GLAXOSMITHKLINE
Hyperkinesia	Lamictal	S	ORAL	75MG Twice per day		GLAXOSMITHKLINE
Euphoric mood	Lamictal	S	ORAL	50MG Twice per day		GLAXOSMITHKLINE
	LEXAPRO	S	ORAL	10MG Per day		
	LITHIUM CARBONATE	S	ORAL			GLAXOSMITHKLINE
	LITHIUM CARBONATE	S	ORAL			GLAXOSMITHKLINE
	LITHIUM CARBONATE	S	ORAL			GLAXOSMITHKLINE
	Solanax	C	ORAL	.4MG Twice per day		GLAXOSMITHKLINE
	Palgin	C	ORAL	1MG Per day		
	ZOLPIDEM TARTRATE	C	ORAL	10MG Per day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Aug-2013	9444570	NON-EXPEDITED			US-PFIZER INC-2013228853	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Effexor	S		UNK		PFIZER
Rash	Zoloft	S		UNK		PFIZER
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Aug-2013	9448225	EXPEDITED (15-DAY)		CA	US-FRI-1000047505	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Patent ductus arteriosus	LEXAPRO	S	TRANSPLACENTAL			FOREST
Talipes						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Aug-2013	9448293	EXPEDITED (15-DAY)		CA	US-FRI-1000047524	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fallot's tetralogy	LEXAPRO	S	TRANSPLACENTAL			FOREST
Patent ductus arteriosus						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Aug-2013	9448383	EXPEDITED (15-DAY)		CA	US-FRI-1000047527	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Heart disease congenital	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Aug-2013	9455706	EXPEDITED (15-DAY)		CA	US-FRI-1000047612	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Craniosynostosis	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2013	9242891	EXPEDITED (15-DAY)		HO	JP-FRI-1000044443		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	LEXAPRO	S	ORAL	10 mg		FOREST
Ventricular tachycardia	RASILEZ	C	ORAL	150 mg		
	NORVASC	C	ORAL	5 mg		
	BUP-4	C	ORAL	20 mg		
	PROTECADIN	C	ORAL	10 mg		
	REMINYL OD	C	ORAL	16 mg		
	NAUZELIN	C	ORAL	20 mg		
	AMITIZA	C	ORAL	24 mg		
	AMLODIPINE	C	ORAL	5 mg		
	MOHRUS	C	TRANSDERMAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2013	9321374	EXPEDITED (15-DAY)		HO	JP-FRI-1000045519		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Serotonin syndrome	LEXAPRO	S	ORAL	10 mg		FOREST
Suicide attempt	LEXAPRO	S	ORAL	20 mg		FOREST
Rhabdomyolysis	ANAFRANIL	S	ORAL	20 mg		
Drug interaction	ANAFRANIL	S	ORAL	50 mg		
	ALCOHOL	S				
	ROHYPNOL	S	ORAL	2 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2013	9458258	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013233349	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Panic attack	Neurontin	S	ORAL	600 mg, 3x/day		PFIZER
Melanocytic naevus	GABAPENTIN	S	ORAL	300 mg, 3x/day		PFIZER
	Lyrica	S		UNK		PFIZER
	Xanax	S		once a day		PFIZER
	PERCOCET	S	ORAL	Oxycodone Hydrochloride 10 mg, Paracetamol 325 mg Take 1 tab every 4 hours		
	LEXAPRO	S	ORAL	20 mg, 1x/day (daily)		
	PROZAC	S		UNK		
	CYMBALTA	C				
	ASPIRIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2013	9458529	EXPEDITED (15-DAY)		CA	US-FRI-1000047717	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypoplastic left heart syndrome	LEXAPRO	S				FOREST
Aorta hypoplasia						
Aortic valve incompetence						
Arteriovenous malformation						
Congenital hydrocephalus						
Mitral valve hypoplasia						
Pulmonary artery stenosis congenital						
Tricuspid valve incompetence						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2013	9459012	NON-EXPEDITED			US-PFIZER INC-2013235313	29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Zoloft	S		UNK		PFIZER
	Effexor XR	S		UNK		PFIZER
	Zithromax	S		UNK		PFIZER
	AMOXIL	S		UNK		
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Aug-2013	9379472	EXPEDITED (15-DAY)		HO,CA,OT	US-FRI-1000046302		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypoplastic left heart syndrome	LEXAPRO	S	TRANSPLACENTAL	5 mg		FOREST
Mitral valve stenosis	LEXAPRO	S	TRANSPLACENTAL	10 mg		FOREST
Aortic valve atresia	ZOLOFT	S	TRANSPLACENTAL	50 mg		
Necrotising enterocolitis neonatal	PROVENTIL HFA	C		2 puffs as needed		
Coarctation of the aorta	CEFDINIR	C		30 ml		
Failure to thrive	NITROFURANTOIN	C		100 mg every 12 hours		
	IBUPROFEN	C		600 mg four times daily as needed		
	ONDANSETRON	C		12 mg		
	ONDANSETRON	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Aug-2013	9464416	EXPEDITED (15-DAY)		DE,CA	US-FRI-1000047788	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrioventricular septal defect	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Aug-2013	9465124	EXPEDITED (15-DAY)		CA	US-FRI-1000047850	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fallot's tetralogy	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Aug-2013	9442435	EXPEDITED (15-DAY)		OT	JP-FRI-1000047441		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicide attempt	LEXAPRO	S	ORAL	10 mg		FOREST
Memory impairment	PAXIL	C	ORAL	3 DF		
Agitation	PAXIL	C	ORAL	2 DF		
	PAXIL	C	ORAL	1 DF		
	LIMAS	C	ORAL			
	LEXOTAN	C	ORAL			
	HYPNOTICS AND SEDATIVES, ANTIANXIETICS	C				

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Aug-2013	9465988	EXPEDITED (15-DAY)		OT	US-FRI-1000030860		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Bronchitis	LEXAPRO	S		10 mg		FOREST
Genital herpes	LEXAPRO	S		20 mg		FOREST
Vaginal abscess	CITALOPRAM	S		40 mg		
Urinary tract infection	LEXAPRO	S		20 mg		FOREST
Vaginal haemorrhage	LEXAPRO	S		10 mg		FOREST
Cellulitis	LEXAPRO	S		10 mg		FOREST
Upper respiratory tract infection	CITALOPRAM	S	ORAL	40 mg		FOREST
Exposure during pregnancy	LEXAPRO	S		10 mg		FOREST
Drug ineffective	LEXAPRO	S		20 mg		FOREST
Foot fracture	ACIPHEX	C		20 mg		
Menstruation irregular	TRINESSA	C				
Fall	ORTHO TRI-CYCLEN	C				
Ligament sprain	ADVIL	C		as needed		
Migraine	VICODIN	C		500/5 mg daily as needed		
Abdominal pain lower	NEXIUM	C	ORAL	20 mg		
Haematuria	PRENATAL VITAMIN	C				
Uterine spasm	PERCOCET	C	ORAL	5/325 MG 1-2 tabs as needed		
Postpartum depression	DOCUSATE	C	ORAL	100 mg		
Cubital tunnel syndrome	AMITRIPTYLINE	C	ORAL	10 mg		
Otitis externa	FOLIC ACID	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Aug-2013	9469836	DIRECT	Y	OT		46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Panic attack	LEXAPRO	S	ORAL	ONE DAILY ORAL		
Drug effect decreased						
Feeling abnormal						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Aug-2013	8589038	EXPEDITED (15-DAY)		DE,HO,OT	US-FRI-1000030861		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Double outlet right ventricle	LEXAPRO	S		10 mg		FOREST
	LEXAPRO	S		20 mg		FOREST
Atrial septal defect	LEXAPRO	S		20 mg		
Fallot's tetralogy	LEXAPRO	S		10 mg		
Cardiomegaly	LEXAPRO	S		10 mg		
Pulmonary hypertension	LEXAPRO	S		10 mg		
Cardiogenic shock	CITALOPRAM	C		40 mg		FOREST
Cardiac failure congestive	CITALOPRAM	C		40 mg		FOREST
Jaundice neonatal	ACIPHEX	C		20 mg		
Atrioventricular block complete	TRINESSA	C				
Nodal rhythm	ORTHO TRI-CYCLEN	C				
Multi-organ failure	ADVIL	C		as needed		
Brain injury	VICODIN	C		500/5 mg daily as needed		
Clostridium difficile infection	NEXIUM	C	ORAL	20 mg		
Coagulopathy	PRENATAL VITAMIN	C				
Serratia infection	PERCOCET	C	ORAL	5/325 mg 1-2 tabs as needed		
Pleural effusion	DOCUSATE	C	ORAL	100 mg		
Acute respiratory failure	AMITRIPTYLINE	C	ORAL	10 mg		
Diarrhoea haemorrhagic	FOLIC ACID	C				
Bronchiolitis						
Cerebrovascular accident						
Conjunctivitis						
Feeding disorder neonatal						
Oral candidiasis						
Otitis media						
Skin disorder						
Urinary tract infection						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Aug-2013	9468337	NON-EXPEDITED			US-PFIZER INC-2013240669	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Decreased appetite	Xanax	S	ORAL	0.125 mg, 4x/day		PFIZER
Anxiety	LEXAPRO	S		2.5 mg, 1x/day		
Dizziness						
Fatigue						
Heart rate decreased						
Tremor						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Aug-2013	9472484	DIRECT	Y			16 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	LEXAPRO	S	ORAL	1 TAB (10 MG) QHS/ bedtime Oral		
Feeling abnormal						
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Aug-2013	9470203	EXPEDITED (15-DAY)		CA	US-FRI-1000047893	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Talipes	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Aug-2013	9471534	EXPEDITED (15-DAY)		CA	US-FRI-1000047895	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Spina bifida	LEXAPRO	S				FOREST
Congenital anomaly						
Congenital hydrocephalus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Aug-2013	9471584	EXPEDITED (15-DAY)		CA	US-FRI-1000047901	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Talipes	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Aug-2013	9471586	EXPEDITED (15-DAY)		CA	US-FRI-1000047903	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Syndactyly	LEXAPRO	S	TRANSPLACENTAL			FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Aug-2013	9400383	EXPEDITED (15-DAY)		LT	JP-FRI-1000046637		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Activation syndrome	LEXAPRO	S	ORAL	10 mg		FOREST
Altered state of consciousness	MEILAX	C	ORAL	2 mg		
Hepatic function abnormal	VEGETAMIN-B	C	ORAL	1 DF		
Overdose						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Aug-2013	9473197	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-18753756	27 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspnoea	SPRYCEL (CML) TABS	S	ORAL			BRISTOL MYERS SQUIBB
Fatigue	LEXAPRO	S				
	VITAMIN C	C				
	OMEGA	C				
	VITAMIN B	C				
	CALCIUM	C				
	MAGNESIUM	C				
	ZINC	C				
	CHLORELLA	C				
	ZINC	C				
	ZYRTEC	C				
	TYLENOL	C				
	SPIRULINA	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Aug-2013	9288161	EXPEDITED (15-DAY)			JP-FRI-1000045083		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Electrocardiogram QT prolonged	LEXAPRO	S	ORAL			FOREST
	LEXAPRO	S	ORAL	10 mg		FOREST
	HORIZON	C	ORAL	2 mg		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Aug-2013	9336706	EXPEDITED (15-DAY)		DS,OT	JP-FRI-1000045731		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebral haemorrhage	LEXAPRO	S	ORAL	20 mg		FOREST
Renal impairment	MEILAX	C	ORAL	1 mg		
Pancytopenia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Aug-2013	9460099	EXPEDITED (15-DAY)		OT	US-FRI-1000047736		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Parkinson's disease	LEXAPRO	S		20 mg		FOREST
Drug ineffective	VIIBRYD	C	ORAL	10 mg		
Prescribed overdose	VIIBRYD	C	ORAL	20 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Aug-2013	9479488	EXPEDITED (15-DAY)			JP-FRI-1000048096		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Weight increased	LEXAPRO	S	ORAL	10 mg		FOREST
	DOGMATYL	S	ORAL	200 mg		
	DOGMATYL	S	ORAL	100 mg		
	MEILAX	C	ORAL	2 mg		
	DEPAS	C	ORAL	0.5 mg		
	DEPAS	C	ORAL	1 mg		
	WYPAX	C	ORAL	1 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Aug-2013	9482732	EXPEDITED (15-DAY)		CA,OT	US-FRI-1000048065	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Heart disease congenital	LEXAPRO	S				FOREST
Coarctation of the aorta						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Sep-2013	9440492	EXPEDITED (15-DAY)		HO,OT	JP-FRI-1000047438		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Electrocardiogram QT prolonged	LEXAPRO	S	ORAL	10 mg		FOREST
Ventricular fibrillation	LEXAPRO	S	ORAL	5 mg		FOREST
Ventricular tachycardia	LANSOPRAZOLE-OD	S	ORAL	15 mg		
Drug interaction	SULPIRIDE	S	ORAL	50 mg		
Decreased appetite	CRAVIT	S	ORAL	1 DF		
Malaise	POLYFUL	C	ORAL	1 Gram		
	POLLAKISU	C	ORAL	4 mg		
	DOPACOL	C	ORAL	100 mg		
	AROTINOLOL HYDROCHLORIDE	C	ORAL	5 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Sep-2013	9451560	EXPEDITED (15-DAY)		HO,OT	US-SANOFI-AVENTIS-2013SA079081	77 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebrovascular accident	PLAVIX	S	ORAL			
Polyp	PLAVIX	S	ORAL			
Lung disorder	LEXAPRO	S	UNKNOWN			
Loss of consciousness	XANAX	S	UNKNOWN			
Fall	PRILOSEC	C				
Contusion	OXYGEN	C	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Sep-2013	9466953	EXPEDITED (15-DAY)		CA	NL-FRI-1000047987		Unknown	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Brain malformation	LEXAPRO	S	TRANSPLACENTAL	10 mg		FOREST
Foetal exposure during pregnancy						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Sep-2013	9465921	EXPEDITED (15-DAY)			BR-FRI-1000047934		Female	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	LEXAPRO	S	ORAL			FOREST
	LEXAPRO	S	ORAL	10 mg		FOREST
	LEXAPRO	S	ORAL	5 mg		
	PRISTIQ	S	ORAL	25 mg		
	SYNTHROID	C	ORAL	100 mcg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Sep-2013	9503590	EXPEDITED (15-DAY)		CA	US-FRI-1000048376	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Encephalocele	LEXAPRO	S	TRANSPLACENTAL			FOREST
Arnold-Chiari malformation						
Congenital anomaly						
Klippel-Feil syndrome						
Renal aplasia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2013	9509051	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17375569	30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Feeling abnormal	ABILIFY	S	ORAL			
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2013	9509057	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17374935	18 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Swollen tongue	ABILIFY	S		red to 2mg		
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2013	9509059	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17370867		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tremor	ABILIFY	S		Also taken 5 mg		
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2013	9509177	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17337718	19 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vision blurred	ABILIFY TABS 5 MG	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2013	9509232	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-19005867	19 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
White blood cell count decreased	ABILIFY	S				
	LEXAPRO	S				
	REMERON	S				
	COGENTIN	S				SANDOZ

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2013	9509234	NON-EXPEDITED		OT	US-BRISTOL-MYERS SQUIBB COMPANY-19005388		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	ABILIFY	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2013	9509251	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17329392	6 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tic	ABILIFY	S		reduced to 5 mg twice a day		
Night sweats	LEXAPRO	S				
Weight decreased	GUANFACINE HYDROCHLORIDE	S				
Back pain						
Corrective lens user						
Depressive symptom						
Disturbance in attention						
Enuresis						
Fatigue						
Somnolence						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2013	9509426	NON-EXPEDITED		OT	US-BRISTOL-MYERS SQUIBB COMPANY-17293515	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Type 2 diabetes mellitus	ABILIFY	S				
Anxiety	LEXAPRO	S				
Weight increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2013	9509543	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17250200		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Lethargy	ABILIFY TABS 5 MG	S				
Anxiety	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2013	9509645	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-18904946		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dystonia	ABILIFY	S				
	CONCERTA	S				
	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2013	9509958	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-18788067	72 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash	ABILIFY TABS 2 MG	S	ORAL	1-2mg also		
Feeling abnormal	ABILIFY TABS 2 MG	S	ORAL	1-2mg also		
Influenza like illness	LEXAPRO	S				
Fatigue	CARBAMAZEPINE	S				
	KLONOPIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2013	9462182	EXPEDITED (15-DAY)		HO	JP-FRI-1000047793		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatic function abnormal	LEXAPRO	S	ORAL	10 mg		FOREST
	MYSLEE	C	ORAL			
	SOLANAX	C	ORAL			
	DOGMATYL	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2013	9492066	EXPEDITED (15-DAY)		HO	JP-FRI-1000048320	33 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Altered state of consciousness	LEXAPRO	S	ORAL	6 tablets		FOREST
Overdose	ISOCLINE	C	ORAL	15 tablets		
	RAVONA	C	ORAL	17 tablets		
	LOBU	C	ORAL	2 tablets		
	DOMPERIDONE	C	ORAL	8 tablets		
	LANSOPRAZOLE	C	ORAL	4 tablets		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2013	9513850	EXPEDITED (15-DAY)		OT	PHEH2013US018891		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myocardial infarction	DIOVAN	S		160 mg, UNK		NOVARTIS
Diabetes mellitus	LEXAPRO	S				
Musculoskeletal discomfort						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Sep-2013	9524117	DIRECT		HO,OT		26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Speech disorder	LEXAPRO	S	ORAL			
Endometriosis						
Fibromyalgia						
Gait disturbance						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Sep-2013	9438827	NON-EXPEDITED			US-PFIZER INC-2013222315	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug interaction	Lyrica	S	ORAL	100 mg, 3x/day		PFIZER
Enuresis	Lyrica	S				PFIZER
Dry mouth	Lyrica	S				PFIZER
Urinary incontinence	OMEPRAZOLE	S		40 mg, 1x/day		
	LEXAPRO	S		10 mg, 1x/day		
	FELODIPINE	S		2.5 mg, 1x/day		
	AMBIEN	S		5 mg, 1x/day		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2013	9326083	EXPEDITED (15-DAY)		OT	JP-FRI-1000045596		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ventricular extrasystoles	LEXAPRO	S	ORAL	10 mg		FOREST
Supraventricular extrasystoles	TAKEPRON	S	ORAL	15 mg		
Drug interaction	PAXIL	S	ORAL	40 mg		
	PREDONINE	S	ORAL	20 mg		
	PREDONINE	S	ORAL	15 mg		
	PREDNISOLONE	S	ORAL	3 mg		
	RISPERDAL	C	ORAL	2 mg		
	SINGULAIR	C	ORAL	10 mg		
	MAGLAX	C	ORAL	990 mg		
	APIDRA	C	SUBCUTANEOUS	24 UT		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2013	9458925	EXPEDITED (15-DAY)		HO	JP-FRI-1000047739		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Activation syndrome	LEXAPRO	S	ORAL	10 mg		FOREST
Disturbance in attention	FLUNITRAZEPAM	C	ORAL	1 mg		
Headache						
Hyperhidrosis						
Tension						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2013	9459006	EXPEDITED (15-DAY)		HO	JP-FRI-1000047740		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicide attempt	LEXAPRO	S	ORAL	10 mg		FOREST
Activation syndrome	RIVOTRIL	C	ORAL	1 mg		
Anxiety	DEPAS	C	ORAL	0.5 mg		
Malaise	RESLIN	C	ORAL	25 mg		
	YOKUKANSANKACHIMPIHANGE	C	ORAL	7.5 Gram		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2013	9459101	EXPEDITED (15-DAY)		HO	JP-FRI-1000047742		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Activation syndrome	LEXAPRO	S	ORAL	10 mg		FOREST
Abdominal pain	REMERON	C	ORAL	15 mg		
Autonomic nervous system imbalance	LEXOTAN	C	ORAL	15 mg		
	SILECE	C	ORAL	4 mg		
	SEROQUEL	C	ORAL	75 mg		
	SEROQUEL	C	ORAL	100 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2013	9529141	EXPEDITED (15-DAY)		OT	JP-FRI-1000024486		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	LEXAPRO	S		10 mg		FOREST
	AMOXAN	S	ORAL	75 mg		
	LEXOTAN	C	ORAL			
	FLUNITRAZEPAM	C	ORAL			
	IRRIBOW	C	ORAL			
	BENZALIN	C	ORAL			
	RAVONA	C	ORAL			
	CYMBALTA	C	ORAL	60 mg		
	SENIRAN	C		6 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2013	9529968	EXPEDITED (15-DAY)		DE	US-FRI-1000048571	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Heart disease congenital	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital anomaly						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2013	9531596	DIRECT	Y			14 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tremor	LEXAPRO	S	ORAL			
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2013	9536426	DIRECT		HO,DS		19 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Glucose tolerance impaired	LEXAPRO	S		10 dose once daily		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Sep-2013	9459007	EXPEDITED (15-DAY)		HO	US-FRI-1000047790	25 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	LEXAPRO	S				FOREST
Trichotillomania	KETAMINE	S				
Anxiety	CLOMIPRAMINE	S				
Anhedonia						
Decreased appetite						
Depressed mood						
Derealisation						
Drug effect incomplete						
Drug interaction						
Hyperphagia						
Hypersomnia						
Illusion						
Sleep disorder						
Weight increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Sep-2013	9533239	EXPEDITED (15-DAY)		OT	US-FRI-1000048699		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Schizophrenia	LEXAPRO	S				FOREST
Off label use						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Sep-2013	9536674	DIRECT	Y			14 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tremor	LEXAPRO	S	ORAL			
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Sep-2013	9537176	DIRECT				45 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Product substitution issue	LEXAPRO	S				
Product formulation issue						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Sep-2013	9160718	NON-EXPEDITED		DE,HO,CA	US-JNJFOC-20130306472		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Respiratory failure	TOPAMAX	S	TRANSPLACENTAL	200-500 mg every day		
Atrial septal defect	LAMICTAL	S	TRANSPLACENTAL			
Sepsis	XANAX	S	TRANSPLACENTAL			
Thrombocytopenia	AMBIEN	S	TRANSPLACENTAL			
Necrotising colitis	TRAZODONE	S	TRANSPLACENTAL			
Cardiac failure congestive	LEXAPRO	S	TRANSPLACENTAL			
Premature baby	ZOLOFT	S	TRANSPLACENTAL			
Ventricular septal defect	DILANTIN	S	TRANSPLACENTAL			
Hypospadias	Z-PACK	S	TRANSPLACENTAL			
Transposition of the great vessels	METFORMIN	S	TRANSPLACENTAL			
Chromosomal deletion						
Cytogenetic abnormality						
Double outlet right ventricle						
Factor V Leiden mutation						
Lung disorder						
Patent ductus arteriosus						
Periventricular leukomalacia						
Tracheitis						
Vascular skin disorder						

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Sep-2013	9517177	NON-EXPEDITED			US-PFIZER INC-2013260096	41 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Zoloft	S		UNK		PFIZER
	Xanax	S		UNK		PFIZER
	Neurontin	S		UNK		PFIZER
	MORPHINE SULFATE	S		UNK		PFIZER
	Robaxin	S		UNK		PFIZER
	ETODOLAC	S		UNK		PFIZER
	TRAMADOL HYDROCHLORIDE	S		UNK		
	WELLBUTRIN	S		UNK		
	PROZAC	S		UNK		
	FLEXERIL	S		UNK		
	AMBIEN	S		UNK		
	CELEXA	S		UNK		
	CYMBALTA	S		UNK		
	LEXAPRO	S		UNK		
	LUNESTA	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Sep-2013	9536586	NON-EXPEDITED		OT	US-JNJFOC-20130306471		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Premature labour	TOPAMAX	S	ORAL	200-500 mg every day		
Exposure during pregnancy	LAMICTAL	S	ORAL	600-800 mg every day		
Postpartum depression	XANAX	S	ORAL	0.25 mg to 1 mg every day		
Emotional disorder	AMBIEN	S	ORAL	50 mg every day		
	TRAZODONE	S	ORAL	100-200 mg every day		
	LEXAPRO	S	ORAL	25 mg every day		
	LEXAPRO	S	ORAL	25 mg every day		
	ZOLOFT	S	ORAL	2010 till present		
	ZOLOFT	S	ORAL	2010 till present		
	DILANTIN	S	ORAL			
	Z-PACK	S	UNKNOWN			
	METFORMIN	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Sep-2013	9549868	EXPEDITED (15-DAY)		DE,OT	US-ACTAVIS-2013-16626	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Toxicity to various agents	CYPROHEPTADINE HYDROCHLORIDE (AMALLC)	S	UNKNOWN	UNK		ACTAVIS MID ATLANTIC
Overdose	Citalopram Hydrobromide (Watson Laboratories)	S	UNKNOWN	UNK		WATSON
Drug interaction	LEXAPRO	S	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Sep-2013	9550659	NON-EXPEDITED			US-SANOFI-AVENTIS-2013SA043992	72 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Asthenia	AUBAGIO	S	ORAL			
Blood pressure fluctuation	AUBAGIO	S	ORAL			
Fatigue	AUBAGIO	S	ORAL			
Tremor	LEXAPRO	S				
Anxiety						
Blood pressure increased						
Gait disturbance						
Heart rate increased						
Nausea						
Paraesthesia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Sep-2013	9553573	DIRECT		DS		46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug dose omission	LEXAPRO	S	ORAL			
Dizziness						
Drug withdrawal syndrome						
Impaired driving ability						
Wrong technique in drug usage process						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Sep-2013	9100164	EXPEDITED (15-DAY)		HO	JP-FRI-1000042573	< 1 DAY	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug withdrawal syndrome neonatal	LEXAPRO	S	TRANSPLACENTAL	20 mg		FOREST
Foetal exposure during pregnancy	REMERON	C	TRANSPLACENTAL			
	RHYTHMY	C	TRANSPLACENTAL			
	MYSLEE	C	TRANSPLACENTAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Sep-2013	9553007	EXPEDITED (15-DAY)		HO	JP-FRI-1000042572		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Threatened labour	LEXAPRO	S	ORAL	20 mg		FOREST
Subchorionic haematoma	REMERON	C	ORAL			
Weight increased	RHYTHMY	C	ORAL			
Pregnancy	MYSLEE	C	ORAL	1 DF		
	CERCINE	C	ORAL	3 DF		
	GASMOTIN	C	ORAL	3 DF		
	SILECE	C	ORAL	1 DF		
	VEGETAMIN-B	C	ORAL	1 DF		
	RISPERDAL	C	TRANSDERMAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Sep-2013	9554325	EXPEDITED (15-DAY)		HO,OT	JP-FRI-1000048416		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hyponatraemia	LEXAPRO	S	ORAL	10 mg		FOREST
Urinary retention	GASMOTIN	S	ORAL	15 mg		
Off label use	CONSTAN	S	ORAL			
Decreased appetite	LENDORMIN	S	ORAL			
Dehydration	LENDORMIN	S	ORAL	0.25 mg		
	OLMETEC	C	ORAL	40 mg		
	METHYCOBAL	C	ORAL	1500 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Sep-2013	9530062	EXPEDITED (15-DAY)		OT	JP-FRI-1000045958		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Thirst	LEXAPRO	S	ORAL	10 mg		FOREST
Decreased appetite	LYRICA	S	ORAL	150 mg		
Nausea	METHYCOBAL	S	ORAL	3 DF		
Depression	ANPLAG	S	ORAL	3 DF		
Off label use						
Poor quality sleep						
Urine output decreased						
Vision blurred						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Sep-2013	9554012	EXPEDITED (15-DAY)			JP-FRI-1000049043		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Palpitations	LEXAPRO	S	ORAL			FOREST
Feeling hot	LUNESTA	C	ORAL			
Hyperhidrosis	ETIZOLAM	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Sep-2013	9560372	EXPEDITED (15-DAY)		HO	CN-FRI-1000049264	53 YR	Female	CHN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Discomfort	LEXAPRO	S	ORAL	10 mg		FOREST
Chest discomfort	LEXAPRO	S	ORAL	1 tab/2 days to 1 tab/5 days		FOREST
Decreased appetite	LEXAPRO	S	ORAL	1 tab/5days		
Back pain						
Blood pressure increased						
Insomnia						
Palpitations						
Tremor						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Sep-2013	9563034	EXPEDITED (15-DAY)		DE,CA	US-FRI-1000049050	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pulmonary hypertension	LEXAPRO	S	TRANSPLACENTAL			FOREST
Atrioventricular septal defect						
Hypoplastic left heart syndrome						
Pulmonary vein stenosis						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Sep-2013	9573331	DIRECT	Y	HO		64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug interaction	LEXAPRO	S	ORAL	1 tablet		
Torsade de pointes						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Oct-2013	9070945	EXPEDITED (15-DAY)		HO	JP-GLAXOSMITHKLINE-B0845771A	78 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash generalised	Lamictal	S	ORAL	25MG Per day		GLAXOSMITHKLINE
Generalised erythema	Lamictal	S	ORAL	50MG Per day		GLAXOSMITHKLINE
Hypersensitivity	Paxil	S	ORAL	12.5MG Per day		GLAXOSMITHKLINE
Nausea	Tramcet	S	ORAL			
Restlessness	Tramcet	S	ORAL			
Red blood cell count decreased	LEXAPRO	S	ORAL	10MG Per day		
White blood cell count decreased	Lyrica	C	ORAL	75MG Twice per day		
Decreased appetite	Milmag	C	ORAL			GLAXOSMITHKLINE
Vomiting	Gasrick D	C	ORAL			
Oropharyngeal pain	Meilax	C	ORAL			
Nasopharyngitis	LITHIUM CARBONATE	C	ORAL	100MG Twice per day		GLAXOSMITHKLINE
Arthralgia	RILMAZAFONE HYDROCHLORIDE	C	ORAL	2MG Per day		
Gait disturbance	Thyradin S	C	ORAL	75MCG Per day		GLAXOSMITHKLINE
Alanine aminotransferase increased						
Aspartate aminotransferase increased						
Blood creatine phosphokinase increased						
Drug eruption						
Drug interaction						
Drug reaction with eosinophilia and systemic symptoms						
Erythema multiforme						
Inappropriate schedule of drug administration						
Malaise						
Ocular hyperaemia						
Pain in extremity						
Pruritus						
Pyrexia						
Rash						
Skin disorder						
Urticaria						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Oct-2013	9499091	EXPEDITED (15-DAY)		HO,OT	US-RB-057907-13	21 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	Suboxone film	S	SUBLINGUAL	Suboxone film		RECKITT BENCKISER
Convulsion	Suboxone film	S	SUBLINGUAL	Suboxone film		RECKITT BENCKISER
Depression	Xanax	S	UNKNOWN	Dosing details unknown		
Insomnia	Ambien	S	ORAL	Dosing details unknown; daily		
Anxiety	Marijuana	S	INHALATION	Dosing details unknown		
Suicidal ideation	Klonopin	S	ORAL			
Affect lability	Prozac	S	UNKNOWN	Dosing details unknown		
Drug abuse	Lexapro	S	UNKNOWN	Dosing details unknown		
Drug dependence	Cymbalta	S	UNKNOWN	Dosing details unknown		
	Zoloft	S	ORAL	Dosing details unknown;		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Oct-2013	9031974	EXPEDITED (15-DAY)		DE,LT,CA,OT	US-PFIZER INC-2013030509		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Maternal exposure timing unspecified	Zoloft	S	TRANSPLACENTAL	UNK		PFIZER
Persistent foetal circulation	LEXAPRO	S	TRANSPLACENTAL	UNK		
Atrial septal defect						
Cleft lip and palate						
Cytogenetic abnormality						
Double outlet right ventricle						
Exomphalos						
Neonatal aspiration						
Neural tube defect						
Pulmonary valve stenosis						
Talipes						
Transposition of the great vessels						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Oct-2013	9580161	EXPEDITED (15-DAY)		OT	PHHY2013US107278	30 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Akathisia	ARIPIPRAZOLE	S		25 mg, UNK		
Dysstasia	QUETIAPINE	S		450 mg, UNK		NOVARTIS
Insomnia	BUSPIRONE	S		30 mg, UNK		
Drug interaction	CLONAZEPAM	S		3 mg, UNK		
	LEXAPRO	S		20 mg, UNK		
	ASENAPINE	S	SUBLINGUAL	5 mg, BID		
	ASENAPINE	S		5 m daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Oct-2013	9581393	EXPEDITED (15-DAY)		OT	US-FRI-1000049275		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ectopic kidney	LEXAPRO	S	TRANSPLACENTAL			FOREST
Atrial septal defect						
Congenital vesicoureteric reflux						
Single functional kidney						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Oct-2013	9431470	EXPEDITED (15-DAY)		HO,OT	US-FRI-1000046980		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Spina bifida	LEXAPRO	S				FOREST
Bradycardia	PRILOSEC	C	TRANSPLACENTAL			
Metabolic acidosis	MACROBID	C	TRANSPLACENTAL			
Anaemia neonatal	TYLENOL	C	TRANSPLACENTAL			
Bronchiolitis						
Croup infectious						
Laryngomalacia						
Nasopharyngitis						
Neurogenic bladder						
Talipes						
Urinary tract infection						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Oct-2013	9587645	EXPEDITED (15-DAY)		CA	US-FRI-1000049277	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ventricular septal defect	LEXAPRO	S	TRANSPLACENTAL			FOREST
Aortic valve disease						
Atrial septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Oct-2013	9587786	EXPEDITED (15-DAY)		HO,OT	US-FRI-1000046979		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Oligohydramnios	LEXAPRO	S				FOREST
Breech presentation	PRILOSEC	C				
Hypertension	MACROBID	C				
Exposure during pregnancy	TYLENOL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Oct-2013	9565067	EXPEDITED (15-DAY)		OT	JP-FRI-1000049260	30 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	LEXAPRO	S	ORAL	210 mg		FOREST
Physical assault	DEPAKENE	C	ORAL	overdose: 800 mg		
	SILECE	C		Overdose: 2 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Oct-2013	9170541	EXPEDITED (15-DAY)		HO,CA,OT	US-JNJFOC-20130310451		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug withdrawal syndrome neonatal	TOPAMAX	S	TRANSPLACENTAL			
Deformity	MIRALAX	S	TRANSPLACENTAL			
Skull malformation	DULCOLAX	S	TRANSPLACENTAL			
Chordee	LEXAPRO	S	TRANSPLACENTAL			
Penile torsion	REGLAN	S	TRANSPLACENTAL			
Prepuce redundant	ZOFRAN	S	TRANSPLACENTAL			
Tachypnoea	METHADONE	S	TRANSPLACENTAL			
Eustachian tube dysfunction	PERCOCET	S	TRANSPLACENTAL			
Otitis media acute	LORTAB	S	TRANSPLACENTAL			
Periventricular leukomalacia	CYMBALTA	S	TRANSPLACENTAL			
Encephalopathy	STADOL	S	TRANSPLACENTAL			
Developmental delay	DILAUDID	S	TRANSPLACENTAL			
Premature baby	NEURONTIN	S	TRANSPLACENTAL			
Pain	PROTONIX	S	TRANSPLACENTAL			
Emotional distress	BENTYL	S	TRANSPLACENTAL			
Social avoidant behaviour	PRENATAL VITAMINS	C	TRANSPLACENTAL			
Muscular weakness						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Oct-2013	9499006	EXPEDITED (15-DAY)		LT	JP-FRI-1000048361		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Loss of consciousness	LEXAPRO	S	ORAL	10 mg		FOREST
Respiratory arrest	RIZE	C	ORAL	15 mg		
Electrocardiogram QT prolonged	CRESTOR	C	ORAL	2.5 mg		
	CO-DIO	C	ORAL	1 DF		
	ALINAMIN-F	C	ORAL	50 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Oct-2013	9609318	EXPEDITED (15-DAY)		HO	US-FRI-1000049715		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cellulitis	LEXAPRO	S	ORAL	10 mg		FOREST
Abscess limb	SOTALOL	C		160 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Oct-2013	9610960	EXPEDITED (15-DAY)		HO,OT	BR-FRI-1000049833		Female	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypothermia	LEXAPRO	S	ORAL	5 mg		FOREST
Somnolence	DIAZEPAM	C	ORAL	5 mg		
Asthenia						
Syncope						
Tremor						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Oct-2013	9612117	NON-EXPEDITED			US-ASTELLAS-2013US009593		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug interaction	Myrbetriq	S	ORAL	25 mg, Unknown/D		ASTELLAS
Anxiety	LEXAPRO	S	UNKNOWN	UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Oct-2013	9454847	EXPEDITED (15-DAY)		HO	JP-MERCK-1308JPN003890	59 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Parkinson's disease	REFLEX	S	ORAL	30mg daily		MERCK
	REFLEX	S	ORAL	15mg daily		MERCK
	REFLEX	S	ORAL	30mg daily		MERCK
	REMERON	S	ORAL	UNK		MERCK
	LEXAPRO	S	ORAL	10 mg daily dose		
	LEXAPRO	S	ORAL	5 mg daily dose		
	LEXAPRO	S	ORAL	10 mg daily dose		
	FLUNITRAZEPAM	C	ORAL	1mg		
	FLUNITRAZEPAM	C				
	ZOLPIDEM TARTRATE	C	ORAL	10 mg		
	ZOLPIDEM TARTRATE	C				
	ESZOPICLONE	C	ORAL	3mg		
	ESZOPICLONE	C				
	RABEPRAZOLE SODIUM	C	ORAL	10mg		
	ETIZOLAM	C	ORAL	0.5 mg		
	ETIZOLAM	C				
	HYDROXYZINE	C	ORAL	50mg		
	HYDROXYZINE	C				
	METFORMIN HYDROCHLORIDE	C	ORAL	750ng		
	MOSAPRIDE CITRATE	C	ORAL	15mg		
	MECOBALAMIN	C	ORAL	1500 Microgram		
	PREGABALIN	C	ORAL	300 mg		
	SENNOSIDES	C	ORAL	1.0g		
	DOXAZOSIN MESYLATE	C	ORAL	4mg		
	DOXAZOSIN MESYLATE	C	ORAL	2mg		
	AZILSARTAN	C	ORAL	20mg		
	DORZOLAMIDE HYDROCHLORIDE	C	INTRAOCULAR	3 drops		MERCK

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Oct-2013	9617225	DIRECT		DS		36 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Libido decreased	LEXAPRO	S	ORAL	1 pill, Once daily, Taken by mouth	8 YR	FOREST
Confusional state						
Erectile dysfunction						
Genital paraesthesia						
Hypoaesthesia						
Memory impairment						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2013	9618668	NON-EXPEDITED			US-PFIZER INC-2013293171	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Zoloft	S		UNK		PFIZER
	CITALOPRAM	S		UNK		
	LEXAPRO	S		UNK		
	PAXIL	S		UNK		
	WELLBUTRIN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2013	9619951	NON-EXPEDITED			US-PFIZER INC-2013292748		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	Xanax	S		UNK		PFIZER
Crying	LEXAPRO	S		UNK		
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Oct-2013	9621432	NON-EXPEDITED			US-PFIZER INC-2013290761	74 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Enbrel	S		UNK		PFIZER
	Zithromax	S		UNK		PFIZER
	REMICADE	S		UNK		
	LEXAPRO	S		UNK		
	ORENCIA	S		UNK		
	PENICILLAMINE	S		UNK		
	CIMZIA	S		UNK		
	RITUXAN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Oct-2013	9468437	EXPEDITED (15-DAY)		DE	IE-PFIZER INC-2013241955	65 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Off label use	Lyrica	S		UNK		PFIZER
Completed suicide	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Oct-2013	9627504	EXPEDITED (15-DAY)		OT	IE-FRI-1000049997	50 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug withdrawal syndrome	LEXAPRO	S	ORAL	20 mg		FOREST
	LEXAPRO	S	ORAL	10 mg		
	LEXAPRO	S	ORAL	5 mg		
	LEXAPRO	S	ORAL			
	LITHIUM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Oct-2013	9629933	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013293820	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Large intestinal haemorrhage	Advil	S		UNK, as needed		PFIZER
Anaemia	Advil	S				PFIZER
Off label use	LEXAPRO	S		10 mg, 1x/day		
	SYNTHROID	C		0.125 mg, 2x/day		
	BENICAR	C		40 mg, 1x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Oct-2013	9631604	NON-EXPEDITED			US-PFIZER INC-2013297318	96 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Off label use	GABAPENTIN	S		3x/day, 300mg in morning and afternoon and 600mg at night		PFIZER
Dizziness	Effexor	S		75 mg, daily		PFIZER
Drug ineffective	Effexor	S		150 mg, daily		PFIZER
	Effexor	S				PFIZER
	LEXAPRO	S		30 mg, 1x/day		
	MAXALT	C		2.5 mg, as needed		
	LORAZEPAM	C		1 mg, as needed		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Oct-2013	9631624	NON-EXPEDITED			US-PFIZER INC-2013298300		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Zithromax	S		UNK		PFIZER
	LEXAPRO	S		UNK		
	CIMZIA	S				
	ORENCIA	S				
	PENICILLAMINE	S				
	RITUXAN	S				
	REMICADE	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Oct-2013	9637181	EXPEDITED (15-DAY)		OT	US-JNJFOC-20131009794		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Electrocardiogram QT prolonged	LEVAQUIN	S	UNKNOWN			
Arrhythmia	ZOFRAN	S	UNKNOWN			
Adverse event	LEXAPRO	S	UNKNOWN			
Drug interaction						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Oct-2013	9638112	NON-EXPEDITED			US-PFIZER INC-2013297974	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Effexor XR	S		UNK		PFIZER
	LEXAPRO	S		UNK		
	Cymbalta	S		UNK		
	PRAVA	S		UNK		
	ORENCIA	S		UNK		
	SIMPONI	S		UNK		
	RITUXAN	S		UNK		
	HUMIRA	S		UNK		
	SAVELLA	S		UNK		
	VIIBRYD	S		UNK		
	WELLBUTRIN SR	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Oct-2013	9638581	EXPEDITED (15-DAY)		OT	AU-BRISTOL-MYERS SQUIBB COMPANY-16034886	40 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abortion spontaneous	ABILIFY TABS 20 MG	S				
Pregnancy	LEXAPRO	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Oct-2013	9640128	NON-EXPEDITED			US-PFIZER INC-2013297291	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Effexor	S		UNK		PFIZER
	Zoloft	S		UNK		PFIZER
	NAPROXEN SODIUM	S		UNK		PFIZER
	PROZAC	S		UNK		
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Oct-2013	9086045	EXPEDITED (15-DAY)		CA,OT	US-FRI-1000042156	< 1 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypoplastic left heart syndrome	LEXAPRO	S	TRANSPLACENTAL			FOREST
Atrial septal defect						
Patent ductus arteriosus						
Pulmonary hypertension						
Ventricular septal defect						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Oct-2013	9524482	NON-EXPEDITED			US-PFIZER INC-2013265665	75 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Off label use	Lyrica	S		unknown dose, 1x/day		PFIZER
Drug ineffective for unapproved indication	Lyrica	S				PFIZER
Drug interaction	LEXAPRO	S		10 mg, 1x/day		
Fatigue	DICYCLOMINE	C		10 mg, as needed		
Arthropathy						
Gait disturbance						
Somnolence						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Oct-2013	9628820	EXPEDITED (15-DAY)			JP-ELI_LILLY_AND_COMPANY-JP201310003334	40 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatic function abnormal	Cymbalta	S	ORAL	20 mg, qd		ELI LILLY AND CO
Hypertriglyceridaemia	LEXAPRO	S	ORAL	UNK		
	LIPIDIL	C	ORAL	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Oct-2013	9644782	NON-EXPEDITED			US-PFIZER INC-2013302115		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myalgia	Zoloft	S	ORAL	100 mg, 1x/day		PFIZER
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Oct-2013	9645293	EXPEDITED (15-DAY)		OT	US-FRI-1000050414		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastrointestinal haemorrhage	LEXAPRO	S				FOREST
Intestinal haemorrhage	PREDNISONE	C				
Abdominal discomfort						
Abdominal pain upper						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Oct-2013	9648460	DIRECT				45 YR	Male	

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Amnesia	LEXAPRO	S	ORAL	1 pill Once daily		
Disturbance in attention						
Premature ageing						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Oct-2013	9654961	EXPEDITED (15-DAY)		OT	US-NAPPMUNDI-USA-2012-0091804	79 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Prescribed overdose	OxyContin (NDA 22-272)	S				PURDUE
Hallucination, auditory	OxyContin (NDA 22-272)	S	ORAL	40 mg, tid		PURDUE
Hallucination, visual	MORPHINE / 00036302/	S	INTRAVENOUS	UNK		
Somnolence	LEXAPRO	S	ORAL	20 mg, UNK		
Crying	LUNESTA	S		3 mg, hs		
	VICODIN	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Oct-2013	9657133	EXPEDITED (15-DAY)		CA	US-FRI-1000050548	< 1 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Congenital anomaly	LEXAPRO	S	TRANSPLACENTAL			FOREST
Atrial septal defect						
Dilatation ventricular						
Heart disease congenital						
Pulmonary valve stenosis						
Right atrial dilatation						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Oct-2013	8795304	EXPEDITED (15-DAY)		DE,OT	US-009507513-1209USA 006060	65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiomegaly	SAPHRIS	S	ORAL	5 mg, qd		MERCK
Self-medication	LEXAPRO	S	ORAL	10 mg, qd		
Completed suicide	LEXAPRO	S	ORAL	20 mg, qd		
Bipolar I disorder	XANAX	S	ORAL	1 mg, qd		
Pneumoconiosis	VICODIN	S	ORAL	UNK		
Left ventricular hypertrophy	TRIAMTERENE	C				
Pulmonary congestion	ATACAND	C				
Visceral congestion	SIMVASTATIN TABLETS, USP	C				MERCK
Nephrosclerosis	FAMOTIDINE	C				MERCK
Toxicity to various agents						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Oct-2013	9661259	EXPEDITED (15-DAY)		OT	US-FRI-1000050468		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Large intestinal haemorrhage	LEXAPRO	S	ORAL	10 mg		FOREST
Anaemia	LEXAPRO	S				FOREST
Blood pressure increased	ADVIL	S		2-3 times daily PRN (up to 6 times daily)		
	ADVIL	S				
	SYNTHROID	C		0.25 mg		
	BENICAR	C		40 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Nov-2013	8818333	NON-EXPEDITED			US-009507513-1209USA 004813		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Muscle twitching	JANUVIA	S		50 mg, qd		MERCK
Insomnia	LEXAPRO	S	ORAL	20 mg, UNK		
Anxiety	LEXAPRO	S		10 UNK, UNK		
	LORAZEPAM	C		UNK		
	METFORMIN	C		500 mg, bid		
	GLYBURIDE	C		5 mg, UNK		
	TRIMETHOPRIM	C		100 mg, UNK		
	SIMVASTATIN	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Nov-2013	9636411	EXPEDITED (15-DAY)		DE,CA	IE-FRI-1000050219		Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Foetal death	LEXAPRO	S	TRANSPLACENTAL			FOREST
Congenital heart valve disorder						
Foetal exposure during pregnancy						
Hydrops foetalis						
Multiple cardiac defects						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Nov-2013	9637906	EXPEDITED (15-DAY)		OT	JP-ELI_LILLY_AND_COMPANY-JP201309008372		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood testosterone increased	Cymbalta	S	ORAL	20 mg, qd		ELI LILLY AND CO
Hyperprolactinaemia	LEXAPRO	S	ORAL	10 mg, qd		
	PRIMPERAN	S	ORAL	1 DF, bid		
	SEPAZON	C	ORAL	1 mg, bid		
	MAGMITT	C	ORAL	660 mg, qd		
	CEPHARANTHIN	C	ORAL	1 mg, bid		
	PROMAC / 01312301/	C	ORAL	75 mg, bid		
	FERROMIA / 00023520/	C	ORAL	50 mg, bid		
	SELBEX	C	ORAL	100 mg, qd		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Nov-2013	9663503	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-LISI20110018	76 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Memory impairment	LISINOPRIL TABLETS 5MG	S	ORAL			
Nausea	LEXAPRO	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Nov-2013	9660486	NON-EXPEDITED			US-PFIZER INC-2013308886	46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Lipitor	S		UNK		PFIZER
	CIPROFLOXACIN	S		UNK		
	METFORMIN HCL	S		UNK		PFIZER
	SERTRALINE HCL	S		UNK		PFIZER
	TETRACYCLINE HCL	S		UNK		PFIZER
	TRAMADOL HCL	S		UNK		PFIZER
	ZOFRAN	S		UNK		
	CYMBALTA	S		UNK		
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Nov-2013	9665940	EXPEDITED (15-DAY)		OT	PHHY2013BR121015		Male	BRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hydrocephalus	GALVUS MET	S	ORAL	2 DF, (metf 850 mg/ vild 50 mg) daily		
Dementia Alzheimer's type	METFORMIN	S	ORAL	850 mg, daily		NOVARTIS
Parkinson's disease	ATENOLOL	S	ORAL	2 DF, (25 mg) daily		
Blood cholesterol increased	LEXAPRO	S	ORAL	1 DF (15mg), daily		
Thyroid disorder	DIAMICRON	S	ORAL	1 DF (60mg), daily		
Gait disturbance						
Mood altered						
Screaming						
Speech disorder						
Tremor						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Nov-2013	8794234	EXPEDITED (15-DAY)		OT	US-MERCK-1209USA005725	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mania	SAPHRIS	S	SUBLINGUAL	20 mg, qpm		MERCK
Inappropriate schedule of drug administration	WELLBUTRIN	S				
Oedema peripheral	LEXAPRO	S				
	ALPRAZOLAM	C		4 mg, qpm		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Nov-2013	9643352	EXPEDITED (15-DAY)		OT	JP-ELI_LILLY_AND_COMPANY-JP201310004590	40 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Syncope	Cymbalta	S	ORAL	20 mg, qd		ELI LILLY AND CO
	LEXAPRO	S	ORAL	10 UNK, UNK		
	LEXAPRO	S	ORAL	UNK		
	LONASEN	C	ORAL	4 mg, UNK		
	LEVOTOMIN / 00038602/	C	ORAL	75 mg, UNK		
	DEPAS	C	ORAL	3 mg, UNK		
	FLUNITRAZEPAM	C	ORAL	UNK		
	GOODMIN	C	ORAL	UNK		
	ALLORIN	C	ORAL	UNK		
	MUCOSTA	C	ORAL	UNK		
	LOXONIN	C	ORAL	UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Nov-2013	9676464	NON-EXPEDITED			US-PFIZER INC-2013314105	62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Zoloft	S		UNK		PFIZER
	Xanax	S		UNK		PFIZER
	VALIUM	S		UNK		
	LEXAPRO	S		UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Nov-2013	8260674	EXPEDITED (15-DAY)		HO,CA,OT	US-JNJFOC-20111109043		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Meningitis neonatal	TOPAMAX	S	TRANSPLACENTAL			
Pharyngotonsillitis	CLINDAMYCIN	S	TRANSPLACENTAL			
Abnormal behaviour	TERBUTALINE	S	TRANSPLACENTAL			
Bronchopulmonary dysplasia	PROMETRIUM	S	TRANSPLACENTAL			
Strabismus	LEXAPRO	S	TRANSPLACENTAL			
Sepsis	LITHIUM CARBONATE	S	TRANSPLACENTAL			
Congenital central nervous system anomaly	ZITHROMAX	S	TRANSPLACENTAL			
Premature baby	BETAMETHASONE	S	TRANSPLACENTAL			
Developmental delay	NIFEDIPINE	S	TRANSPLACENTAL			
Enlarged clitoris	AMPICILLIN	S	TRANSPLACENTAL			
Apgar score low						
Asthma						
Attention deficit/hyperactivity disorder						
Cleft lip and palate						
Emotional disorder						
Gastrooesophageal reflux disease						
Intraventricular haemorrhage neonatal						
Lung disorder						
Malocclusion						
Nasal septum deviation						
Patent ductus arteriosus						
Retinopathy of prematurity						
Sleep apnoea syndrome						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Nov-2013	8471999	EXPEDITED (15-DAY)		HO,OT	US-JNJFOC-20111109040		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Premature rupture of membranes	TOPAMAX	S	ORAL			
Premature delivery	TOPAMAX	S	ORAL			
Exposure during pregnancy	TOPAMAX	S	ORAL			
Amniotic cavity infection	TOPAMAX	S	ORAL			
Bipolar disorder	CLINDAMYCIN	S	VAGINAL			
Premature separation of placenta	TERBUTALINE	S	ORAL			
Emotional distress	PROMETRIUM	S	ORAL			
	LEXAPRO	S	ORAL			
	LITHIUM CARBONATE	S	ORAL			
	ZITHROMAX	S	UNKNOWN			
	BETAMETHASONE	S	UNKNOWN			
	NIFEDIPINE	S	UNKNOWN			
	AMPICILLIN	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Nov-2013	8774272	EXPEDITED (15-DAY)		HO	JP-009507513-2012SP014090	49 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dizziness	PEGINTRON	S	SUBCUTANEOUS	1.3 Microgram per kilogram, qw		MERCK
Asthenia	PEGINTRON	S	SUBCUTANEOUS	1.5 Microgram per kilogram, qw		MERCK
	PEGINTRON	S	SUBCUTANEOUS	1.5 Microgram per kilogram, qw		MERCK
	PEGINTRON	S	SUBCUTANEOUS	40 Microgram per kilogram, qw		MERCK
	PEGINTRON	S	SUBCUTANEOUS	60 Microgram per kilogram, qw		MERCK
	PEGINTRON	S	SUBCUTANEOUS	80 Microgram per kilogram, qw		MERCK
	REBETOL	S	ORAL	800 mg, qd		MERCK
	REBETOL	S	ORAL	400 mg, QD		MERCK
	REBETOL	S	ORAL	800 mg, QD		MERCK
	TELAVIC	S	ORAL	2250 mg, QD		
	TELAVIC	S	ORAL	1500 mg, QD		
	TELAVIC	S	ORAL	Daily dose unknown		
	DESYREL	S	ORAL	50 mg, QD, formulation:por		
	LEXAPRO	S	ORAL	10 mg, QD, formulation:por		
	MUCOSTA	C	ORAL	300 mg, qd		
	LOXONIN	C	ORAL	prn, Formulation: por		
	APHTASOLON	C	PARENTERAL	prn, formulation:EXT		
	HACHIAZULE GARGLE	C	PARENTERAL	prn, formulation: EXT		
	PURSENNID (sennosides)	C	ORAL	prn, Formulation:por		
	CELESTODERM V	C	TOPICAL	1 g, qd		
	FULMETA	C	TOPICAL	UNK UNK, prn		
	NAUZELIN	C	ORAL	3 DF, qd		
	LAC-B	C	ORAL	3 g, qd, formulation: por		
	PRIMPERAN	C	INTRAVENOUS	1 DF, qd		
	VITAMEDIN CAPSULES	C		3 DF, qd		

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Nov-2013	8995914	EXPEDITED (15-DAY)		HO,DS,OT	US-009507513-2010SP063654		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypercoagulation	NUVARING	S	VAGINAL			MERCK
Muscle strain	NUVARING	S				MERCK
Fibromyalgia	NUVARING	S				MERCK
Pulmonary embolism	NUVARING	S				MERCK
Cerebellar haemorrhage	LEXAPRO	S				
Vertigo	REGLAN	S				
Epstein-Barr virus infection	COUMADIN	S				
Dyspnoea	COUMADIN	S				
Acute sinusitis						
Back pain						
Breast disorder						
Bursitis						
Concussion						
Depression						
Drug hypersensitivity						
Drug intolerance						
Dystonia						
Fatigue						
Feeling jittery						
Folate deficiency						
Gastrooesophageal reflux disease						
Headache						
Herpes simplex						
Inappropriate schedule of drug administration						
Influenza like illness						
Insomnia						
Iron deficiency anaemia						
Lichenoid keratosis						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Loss of consciousness						
Lymphadenectomy						
Mastoptosis						
Metrorrhagia						
Migraine						
Off label use						
Ovarian cyst						
Pain						
Pelvic pain						
Pharyngitis						
Sleep apnoea syndrome						
Vaginal discharge						
Viral infection						
Vitamin B12 deficiency						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Nov-2013	9636353	EXPEDITED (15-DAY)		HO,LT	AU-FRI-1000050319		Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depressed level of consciousness	LEXAPRO	S	ORAL	30 mg		FOREST
Overdose	ALPRAZOLAM	S	ORAL	1 mg		
Drug interaction	METHYLPREDNISOLONE	S	OTHER	40 mg		
	SODIUM VALPROATE	S	ORAL	1.5 Gram		
	MIRTAZAPINE	C	ORAL	75 mg		
	RABEPRAZOLE	C	ORAL	20 mg		
	SALBUTAMOL	C		6 DF		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Nov-2013	9176567	EXPEDITED (15-DAY)		DE	US-JNJFOC-20130306847		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Completed suicide	CONCERTA	S	ORAL			
Overdose	ADDERALL	S	UNKNOWN			
	LEXAPRO	S	UNKNOWN			
	VYVANSE	C	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Nov-2013	9181563	NON-EXPEDITED		OT	US-PFIZER INC-2013091534	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Glucose tolerance impaired	Zoloft	S		100 mg, UNK		PFIZER
Oedema peripheral	LEXAPRO	S		10 mg, UNK		
Weight increased	AMITRIPTYLINE	S		25 mg, UNK		
Increased appetite	WARFARIN	C		8 mg, every Tuesday, Wednesday, Friday, Saturday and Sunday		
Asthenia						
Muscle spasms						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Nov-2013	9648169	EXPEDITED (15-DAY)		HO	PHEH2013US022324		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tremor	COMBIPATCH	S	TRANSDERMAL	UNK UKN, UNK		NOVARTIS
Anxiety	COMBIPATCH	S	TRANSDERMAL	UNK UKN, UNK		NOVARTIS
Speech disorder	LEXAPRO	S		UNK UKN, UNK		
Blood thyroid stimulating hormone decreased						
Merycism						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Nov-2013	9526444	EXPEDITED (15-DAY)		HO,DS	US-TEVA-432072USA	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Parkinsonism	CLOZAPINE	S				IVAX
Obsessive-compulsive disorder	luvox	S				
Toxicity to various agents	Lexapro	S				
Drug interaction	BENZATROPINE MESILATE	C				
Cogwheel rigidity	depakote	C				
Akathisia	prilosec	C				
	antidepressant	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Nov-2013	9690854	EXPEDITED (15-DAY)		OT	US-FRI-1000051153		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Homicide	LEXAPRO	S				FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Nov-2013	9693503	EXPEDITED (15-DAY)		OT	AU-ABBVIE-13P-008-1157517-00	57 YR	Female	AUS

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Petit mal epilepsy	SODIUM VALPROATE	S	UNKNOWN			
Cogwheel rigidity	LEXAPRO	S	UNKNOWN			
Extrapyramidal disorder	EDRONAX	S				
	MODURETIC	C				
	NEXIUM (ESOMEPRAZOLE SODIUM)	C				
	ASPIRIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Nov-2013	9695780	EXPEDITED (15-DAY)		HO,OT	JP-FRI-1000051453		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood creatine phosphokinase increased	LEXAPRO	S	ORAL			FOREST
Overdose	LEXAPRO	S	ORAL			FOREST
Hyperhidrosis	MEILAX	C	ORAL			
Depressed level of consciousness						
Off label use						
Pyrexia						
Tachycardia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Nov-2013	9696139	EXPEDITED (15-DAY)		HO	CN-FRI-1000051458	63 YR	Female	CHN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Asthenia	LEXAPRO	S	ORAL	5 mg		FOREST
Confusional state	LEXAPRO	S	ORAL	10 mg		FOREST
Decreased appetite	ZOLOFT	C	ORAL	1 DF		
Muscle tightness	OMEPRAZOLE	C	ORAL			
Gastrooesophageal reflux disease	METOPROLOL	C	ORAL			
Off label use						
Parkinson's disease						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Nov-2013	9681870	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013320824	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Off label use	Lyrica	S		75 mg, daily		PFIZER
Heart rate increased	Lyrica	S		50 mg, 2x/day		PFIZER
Palpitations	Lyrica	S				PFIZER
Dyspnoea	LEXAPRO	S		UNK		
Panic attack	LEXAPRO	S				
Anxiety						
Chest discomfort						
Depression						
Feeling hot						
Myalgia						
Vision blurred						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Nov-2013	9382003	EXPEDITED (15-DAY)		CA,OT	JP-FRI-1000046398	38 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sperm concentration decreased	LEXAPRO	S	ORAL	10 mg		FOREST
Spermatozoa progressive motility decreased	LEXAPRO	S	ORAL	20 mg		FOREST
	LEXAPRO	S	ORAL	20 mg		FOREST
	MEILAX	C	ORAL	2 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Nov-2013	9675058	EXPEDITED (15-DAY)		HO	JP-FRI-1000050799	48 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrioventricular block	LEXAPRO	S	ORAL	20 mg		FOREST
	REFLEX	C	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Nov-2013	9700549	NON-EXPEDITED			US-PFIZER INC-2013331159	48 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Effexor	S		UNK		PFIZER
	LEXAPRO	S		UNK		
	WELLBUTRIN	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Nov-2013	9690943	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013326280	75 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hip fracture	Xanax	S		0.5 mg in the morning and 1.5 mg at night		PFIZER
Mental disorder	Preparation H	S		UNK, as needed		PFIZER
Intentional drug misuse	REMERON	S		30 mg, daily		
	LEXAPRO	S		25 mg, daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Nov-2013	9708787	EXPEDITED (15-DAY)		OT	JP-FRI-1000051631	70 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dizziness postural	LEXAPRO	S	ORAL	10 mg		FOREST

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Nov-2013	9537853	EXPEDITED (15-DAY)		HO,OT	JP-FRI-1000040028		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Palpitations	LEXAPRO	S	ORAL	10 mg		FOREST
Dyspnoea	ADETPHOS	C	ORAL	300 mg		
Dizziness	REBAMIPIDE	C	ORAL	300 mg		
Feeling hot	GASMOTIN	C	ORAL	15 mg		
Nausea	ALOSITOL	C	ORAL	100 mg		
Paraesthesia	TAKEPRON	C	ORAL	15 mg		
	MYSLEE	C	ORAL	10 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Nov-2013	9716625	NON-EXPEDITED			US-PFIZER INC-2013338910		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Contusion	Zoloft	S		UNK		PFIZER
	LEXAPRO	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Dec-2013	9721584	EXPEDITED (15-DAY)		OT	US-009507513-1311USA 012141		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hip fracture	REMERON	S		30 mg, qd		MERCK
Unevaluable event	LEXAPRO	S		25 mg, qd		
Off label use	XANAX	S		dose of 0.5mg in the morning and 1.5mg at night , bid		
	PREPARATION H HEMORRHOIDAL OINTMENT	S		UNK, prn		