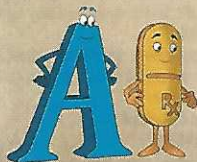
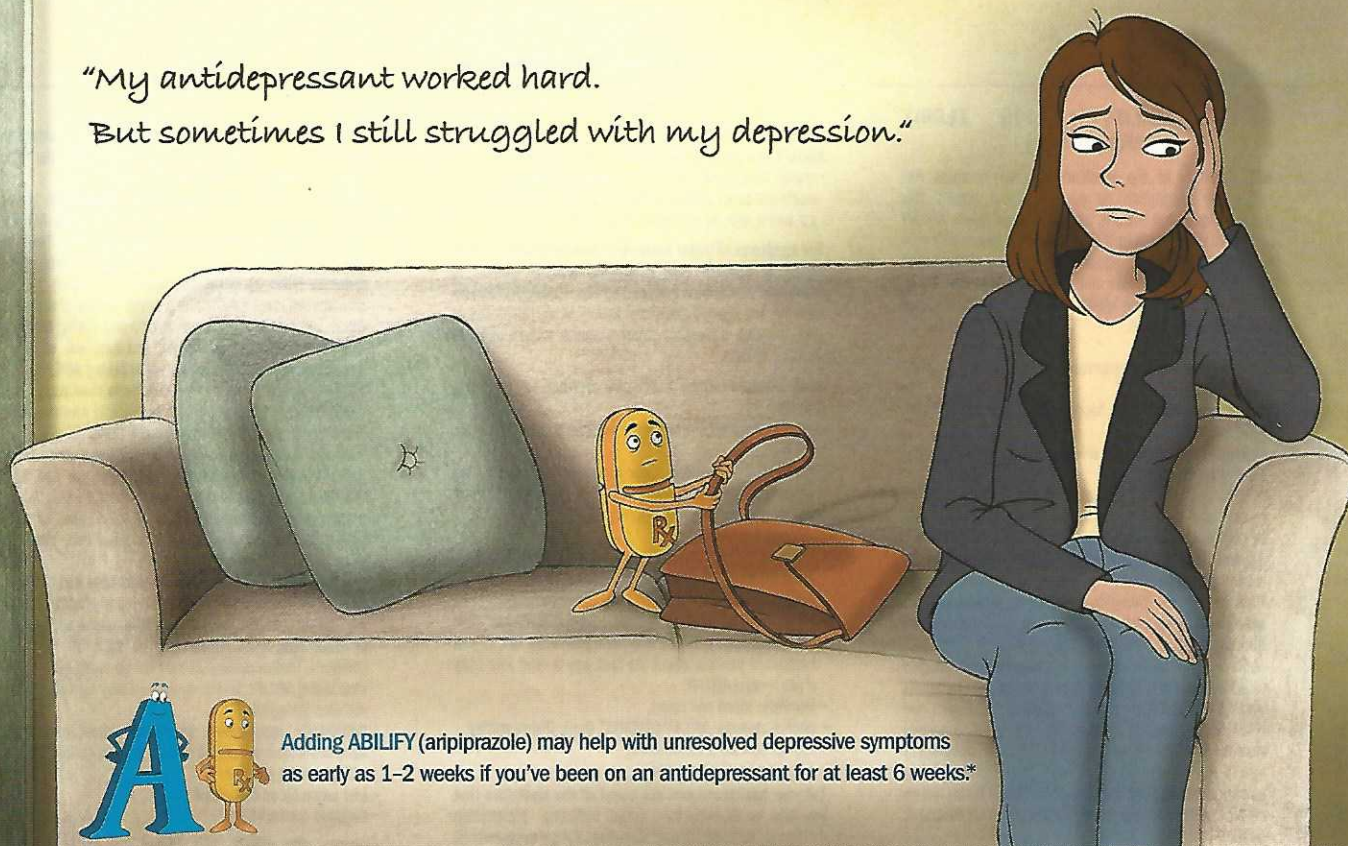


"My antidepressant worked hard.
But sometimes I still struggled with my depression."



Adding ABILIFY (aripiprazole) may help with unresolved depressive symptoms as early as 1–2 weeks if you've been on an antidepressant for at least 6 weeks.*

ABILIFY is a prescription medicine used to treat depression in adults as an add-on treatment to an antidepressant when an antidepressant alone is not enough.

Important Safety Information

Elderly patients with dementia-related psychosis (e.g., an inability to perform daily activities due to increased memory loss) taking ABILIFY have an increased risk of death or stroke. ABILIFY is not approved for treating these patients. Antidepressants can increase suicidal thoughts and behaviors in children, teens, and young adults. Serious mental illnesses are themselves associated with an increase in the risk of suicide. When taking ABILIFY, call your doctor right away if you have new or worsening depression symptoms, unusual changes in behavior, or thoughts of suicide. Patients and their caregivers should be especially observant within the first few months of treatment or after a change in dose. Approved only for adults 18 and over with depression.

- Call your doctor if you develop very high fever, rigid muscles, shaking, confusion, sweating, or increased heart rate and blood pressure, as these may be signs of a rare but potentially fatal condition called **neuroleptic malignant syndrome (NMS)**.
- If you have **diabetes** or have risk factors or symptoms of diabetes, your blood sugar should be monitored. High blood sugar has been reported with ABILIFY and medicines like it. In some cases, extreme high blood sugar can lead to coma or death.

*Based on 6-week clinical studies comparing ABILIFY + antidepressant versus antidepressant alone.

- If you develop uncontrollable facial or body movements, call your doctor, as these may be signs of **tardive dyskinesia (TD)**. TD may become permanent and the risk of TD may increase with the length of treatment and the overall dose. While TD can develop after taking the medicine at low doses for short periods, this is much less common. There is no known treatment for TD, but it may go away partially or completely if the medicine is stopped.
- **Other risks** may include lightheadedness upon standing, decreases in white blood cells (which can be serious), seizures, trouble swallowing, or impairment in judgment or motor skills. Until you know how ABILIFY affects you, you should not drive or operate machinery.

The common side effects in adults in clinical trials ($\geq 10\%$) include nausea, vomiting, constipation, headache, dizziness, **an inner sense of restlessness or need to move (akathisia)**, anxiety, and insomnia. Tell your doctor about all the medicines you're taking, since there are some risks for drug interactions. You should avoid alcohol while taking ABILIFY.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.


Please read the additional Important Information about ABILIFY on the adjacent page.

Learn about a **FREE trial offer** at ABILIFYfreeOffer.com or 1-800-393-5553

ABILIFY
(aripiprazole)
2 mg, 5 mg Tablet

Ask your doctor about the option of adding ABILIFY.

 Bristol-Myers Squibb Company | PATIENT ASSISTANCE FOUNDATION
This non-profit organization provides assistance to qualifying patients with financial hardship who generally have no prescription insurance. Contact 1-800-736-0003 or visit www.bmspa.org for more information.

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March 2014 03US14EBC0021

ABILIFY® (a BIL i fi) ONLY (aripiprazole)

This summary of the Medication Guide contains risk and safety information for patients about ABILIFY. This summary does not include all information about ABILIFY and is not meant to take the place of discussions with your healthcare professional about your treatment. Please read this important information carefully before you start taking ABILIFY and discuss any questions about ABILIFY with your healthcare professional.

What is the most important information I should know about ABILIFY?

Serious side effects may happen when you take ABILIFY, including:

• Increased risk of death in elderly patients with dementia-related psychosis:

Medicines like ABILIFY can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). ABILIFY is not approved for the treatment of patients with dementia-related psychosis.

• Risk of suicidal thoughts or actions: Antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions:

Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions including people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.

How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?

- Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying, attempts to commit suicide, new or worse depression, new or worse anxiety, feeling very agitated or restless, panic attacks, trouble sleeping (insomnia), new or worse irritability, acting aggressive, being angry, or violent, acting on dangerous impulses, an extreme increase in activity and talking (mania), other unusual changes in behavior or mood.

What else do I need to know about antidepressant medicines?

- **Never stop an antidepressant medicine without first talking to a healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.
- **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.
- **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.
- **Not all antidepressant medicines prescribed for children are FDA approved for use in children.** Talk to your child's healthcare provider for more information.

What is ABILIFY (aripiprazole)?

ABILIFY is a prescription medicine used to treat:

- major depressive disorder in adults, as an add-on treatment to an antidepressant medicine when you do not get better with an antidepressant alone.

The symptoms of major depressive disorder (MDD) include feeling of sadness and emptiness, loss of interest in activities that you once enjoyed and loss of energy, problems focusing and making decisions, feeling of worthlessness or guilt, changes in sleep or eating patterns, and thoughts of death or suicide.

What should I tell my healthcare provider before taking ABILIFY?

Before taking ABILIFY, tell your healthcare provider if you have or had:

- diabetes or high blood sugar in you or your family; your healthcare provider should check your blood sugar before you start ABILIFY and also during therapy.
- seizures (convulsions).
- low or high blood pressure.
- heart problems or stroke.
- pregnancy or plans to become pregnant.
- breast-feeding or plans to breast-feed. ABILIFY can pass into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you receive ABILIFY.
- low white blood cell count.
- phenylketonuria. ABILIFY DISCMLT Orally Disintegrating Tablets contain phenylalanine.
- any other medical conditions.

Tell your healthcare provider about all the medicines that you take or recently have taken, including prescription medicines, non-prescription medicines, herbal supplements, and vitamins.

ABILIFY and other medicines may affect each other causing possible serious side effects. ABILIFY may affect the way other medicines work, and other medicines may affect how ABILIFY works.

Your healthcare provider can tell you if it is safe to take ABILIFY with your other medicines. Do not start or stop any medicines while taking ABILIFY without talking to your healthcare provider first. Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

How should I take ABILIFY?

- Take ABILIFY exactly as your healthcare provider tells you to take it. Do not change the dose or stop taking ABILIFY yourself.
- ABILIFY can be taken with or without food.
- ABILIFY tablets should be swallowed whole.
- If you miss a dose of ABILIFY, take the missed dose as soon as you remember. If it is almost time for the next dose, just skip the missed dose and take your next dose at the regular time. Do not take two doses of ABILIFY at the same time.
- If you take too much ABILIFY, call your healthcare provider or poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.

What should I avoid while taking ABILIFY?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how ABILIFY affects you. ABILIFY may make you drowsy.
- Do not drink alcohol while taking ABILIFY.
- Avoid getting over-heated or dehydrated.
 - Do not over-exercise.
 - In hot weather, stay inside in a cool place if possible.
 - Stay out of the sun. Do not wear too much or heavy clothing.
 - Drink plenty of water.

What are the possible side effects of ABILIFY?

Serious side effects have been reported with ABILIFY including:

- **Neuroleptic malignant syndrome (NMS):** Tell your healthcare provider right away if you have some or all of the following symptoms: high fever, stiff muscles, confusion, sweating, changes in pulse, heart rate, and blood pressure.

These may be symptoms of a rare and serious condition that can lead to death. Call your healthcare provider right away if you have any of these symptoms.

- **High blood sugar (hyperglycemia):** Increases in blood sugar can happen in some people who take ABILIFY (aripiprazole). Extremely high blood sugar can lead to coma or death. If you have diabetes or risk factors for diabetes (such as being overweight or a family history of diabetes), your healthcare provider should check your blood sugar before you start ABILIFY and during therapy.

Call your healthcare provider if you have any of these symptoms of high blood sugar while taking ABILIFY:

- feel very thirsty, need to urinate more than usual, feel very hungry, feel weak or tired, feel sick to your stomach, feel confused, or your breath smells fruity.
- **Increase in weight:** Weight gain has been reported in patients taking medicines like ABILIFY, so you and your healthcare provider should check your weight regularly. For children and adolescent patients (6 to 17 years of age) weight gain should be compared against that expected with normal growth.
- **Difficulty swallowing:** may lead to aspiration and choking.
- **Tardive dyskinesia:** Call your healthcare provider about any movements you cannot control in your face, tongue, or other body parts. These may be signs of a serious condition. Tardive dyskinesia may not go away, even if you stop taking ABILIFY. Tardive dyskinesia may also start after you stop taking ABILIFY.
- **Orthostatic hypotension (decreased blood pressure):** lightheadedness or fainting when rising too quickly from a sitting or lying position.
- **Low white blood cell count**
- **Seizures (convulsions)**

Common side effects with ABILIFY in adults include nausea, inner sense of restlessness/need to move (akathisia), vomiting, anxiety, constipation, insomnia, headache, restlessness, dizziness.

These are not all the possible side effects of ABILIFY. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about ABILIFY


- Store ABILIFY at room temperature, between 59°F to 86°F. Opened bottles of ABILIFY Oral Solution can be used for up to 6 months after opening, but not beyond the expiration date on the bottle. Keep ABILIFY and all medicines out of the reach of children.
- Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ABILIFY for a condition for which it was not prescribed. Do not give ABILIFY to other people, even if they have the same condition. It may harm them.
- This summary contains the most important information about ABILIFY. If you would like more information, talk with your healthcare provider. For more information about ABILIFY visit www.abilify.com.

Tablets manufactured by Otsuka Pharmaceutical Co, Ltd, Tokyo, 101-8535 Japan or Bristol-Myers Squibb Company, Princeton, NJ 08543 USA

Orally Disintegrating Tablets, Oral Solution, and Injection manufactured by Bristol-Myers Squibb Company, Princeton, NJ 08543 USA

Distributed and marketed by Otsuka America Pharmaceutical, Inc, Rockville, MD 20850 USA

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 **Otsuka** Otsuka America Pharmaceutical, Inc.
03US13EC0033 Rev August 2013 © 2013
Otsuka Pharmaceutical Co, Ltd, Tokyo, 101-8535 Japan

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