

<p style="text-align: center;"><b>MEDICATION GUIDE</b>  <b>ABILIFY MAINTENA® (a-BIL-i-fy main-TEN-a)</b>  <b>(aripiprazole) for extended-release injectable suspension, for intramuscular use</b></p>
<p><b>What is the most important information I should know about ABILIFY MAINTENA?</b>  <b>ABILIFY MAINTENA may cause serious side effects, including:</b></p> <ul style="list-style-type: none"> <li>• <b>Increased risk of death in elderly people with dementia-related psychosis.</b> ABILIFY MAINTENA increases the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). ABILIFY MAINTENA is not for the treatment of people with dementia-related psychosis.</li> </ul>
<p><b>What is ABILIFY MAINTENA?</b>  ABILIFY MAINTENA is a prescription medicine given by injection by a healthcare provider:</p> <ul style="list-style-type: none"> <li>• for the treatment of schizophrenia in adults</li> <li>• alone as maintenance treatment of bipolar I disorder in adults</li> </ul> <p>It is not known if ABILIFY MAINTENA is safe and effective in children under 18 years of age.</p>
<p><b>Who should not receive ABILIFY MAINTENA?</b>  <b>Do not receive ABILIFY MAINTENA if you</b> are allergic to aripiprazole or any of the ingredients in ABILIFY MAINTENA. See the end of this Medication Guide for a complete list of ingredients in ABILIFY MAINTENA.</p>
<p><b>Before receiving ABILIFY MAINTENA, tell your healthcare provider</b> about all of your medical conditions, including if you:</p> <ul style="list-style-type: none"> <li>• have never taken aripiprazole before</li> <li>• have or had diabetes or high blood sugar or a family history of diabetes or high blood sugar</li> <li>• have or had high levels of total cholesterol, LDL cholesterol, or triglycerides, or low levels of HDL cholesterol</li> <li>• have or had low or high blood pressure</li> <li>• have or had heart problems or a stroke</li> <li>• have or had a low white blood cell count</li> <li>• have or had seizures (convulsions)</li> <li>• have problems that may affect you receiving an injection in your arm or buttocks</li> <li>• are pregnant or plan to become pregnant. It is not known if ABILIFY MAINTENA will harm your unborn baby. Receiving ABILIFY MAINTENA during your third trimester of pregnancy may cause your baby to have abnormal muscle movements or withdrawal symptoms after birth. Talk to your healthcare provider about the risk to your unborn baby if you receive ABILIFY MAINTENA during pregnancy <ul style="list-style-type: none"> <li>○ Tell your healthcare provider right away if you become pregnant or think that you are pregnant during treatment with ABILIFY MAINTENA.</li> <li>○ If you become pregnant while receiving ABILIFY MAINTENA, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or go to <a href="http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/">http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/</a></li> </ul> </li> <li>• are breastfeeding or plan to breastfeed. ABILIFY MAINTENA can pass into your breast milk and it is not known if it may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you receive ABILIFY MAINTENA.</li> </ul> <p><b>Tell your healthcare provider about all the medicines you take</b>, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements.</p>

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

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

#### **How should I receive ABILIFY MAINTENA?**

- Follow your ABILIFY MAINTENA treatment schedule exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much ABILIFY MAINTENA you will receive and when you will receive it.
- ABILIFY MAINTENA is an injection given in your arm or buttock by your healthcare provider 1 time every month.
- There are 2 ways to start (initiate) treatment with ABILIFY MAINTENA if you currently take an antipsychotic medicine by mouth (oral):
  - 1-day initiation: You will receive 2 injections of ABILIFY MAINTENA on your first day of treatment. Each injection will be given in a different injection site. You will also take 1 dose of aripiprazole by mouth.

#### **OR**

- 14-day initiation: You will receive 1 injection of ABILIFY MAINTENA. You will continue to take your oral aripiprazole or your current antipsychotic medicine by mouth for 14 days in a row.
- You should not miss a dose of ABILIFY MAINTENA. If you miss a dose for some reason, call your healthcare provider right away to discuss what you should do next.

#### **What should I avoid while receiving ABILIFY MAINTENA?**

- Do not drive a car, operate machinery, or do other dangerous activities until you know how ABILIFY MAINTENA affects you. ABILIFY MAINTENA may affect your judgement, thinking, or motor skills.
- Do not drink alcohol during treatment with ABILIFY MAINTENA.
- Do not become too hot or dehydrated during treatment with ABILIFY MAINTENA.
  - Do not exercise too much.
  - In hot weather, stay inside in a cool place if possible.
  - Stay out of the sun.
  - Do not wear too much clothing or heavy clothing.
  - Drink plenty of water.

#### **What are the possible side effects of ABILIFY MAINTENA?**

**ABILIFY MAINTENA may cause serious side effects, including:**

- See "What is the most important information I should know about ABILIFY MAINTENA?"
- **Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death.**
- **Neuroleptic malignant syndrome (NMS), a serious condition that can lead to death.** Call your healthcare provider or go to the nearest emergency room right away if you have some or all of the following symptoms of NMS:
  - high fever
  - stiff muscles

- confusion
- changes in pulse, heart rate, and blood pressure
- sweating

- **Uncontrolled body movements (tardive dyskinesia).** ABILIFY MAINTENA may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop receiving ABILIFY MAINTENA. Tardive dyskinesia may also start after you stop receiving ABILIFY MAINTENA.

- **Problems with your metabolism such as:**

- **high blood sugar (hyperglycemia) and diabetes:** Increases in blood sugar can happen in some people who receive ABILIFY MAINTENA. 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 receiving ABILIFY MAINTENA and during your treatment.

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

- |                             |                                               |
|-----------------------------|-----------------------------------------------|
| ▪ 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 |

- **Increased fat levels (cholesterol and triglycerides) in your blood.**
- **Weight gain.** You and your healthcare provider should check your weight regularly during treatment with ABILIFY MAINTENA.
- **Unusual and uncontrollable (compulsive) urges.** Some people receiving ABILIFY MAINTENA have had unusual strong urges to gamble and gambling that cannot be controlled (compulsive gambling). Other compulsive urges including sexual urges, shopping, and eating or binge eating. If you or your family members notice that you are having unusual urges or behaviors, talk to your healthcare provider.
- **Decreased blood pressure (orthostatic hypotension).** You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.
- **Falls.** ABILIFY MAINTENA may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position (orthostatic hypotension), and can slow your thinking and motor skills which may lead to falls that can cause fractures or other injuries.
- **Low white blood cell count.** Your healthcare provider may do blood tests during your first few months of treatment with ABILIFY MAINTENA.
- **Seizures (convulsions)**
- **Sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities.** See "What should I avoid while receiving ABILIFY MAINTENA?"
- **Problems controlling your body temperature so that you feel too warm.** See "What should I avoid while receiving ABILIFY MAINTENA?"
- **Difficulty swallowing** that can cause food or liquid to get into your lungs

**The most common side effects of ABILIFY MAINTENA include:** weight gain, restlessness or feeling like you need to move (akathisia), injection site pain, or sleepiness (sedation).

These are not all the possible side effects of ABILIFY MAINTENA.

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

**General information about the safe and effective use of ABILIFY MAINTENA.**

If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about ABILIFY MAINTENA that is written for healthcare professionals.

**What are the ingredients in ABILIFY MAINTENA?**

**Active ingredient:** aripiprazole monohydrate

**Inactive ingredients:** carboxymethylcellulose sodium, mannitol, sodium phosphate monobasic monohydrate and sodium hydroxide

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For more information, go to [www.ABILIFYMAINTENA.com](http://www.ABILIFYMAINTENA.com) or call 1-800-441-6763.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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