

STARTING THE CONVERSATION ABOUT A *once-monthly** TREATMENT OPTION



*You should continue to take your current bipolar I disorder medication for 2 weeks after your first treatment with ABILIFY MAINTENA.



Here are some questions that can make having a discussion with your healthcare provider—and help you determine whether once-monthly* ABILIFY MAINTENA® (aripiprazole) is right for you.

- Could a once-monthly treatment like ABILIFY MAINTENA be an appropriate option for me?

- What are the possible side effects of ABILIFY MAINTENA? _____

- Can ABILIFY MAINTENA help give me more time without a mood episode? _____

- Do my bipolar symptoms need to be under control before starting ABILIFY MAINTENA?

- Do I need to stay on my current treatment after starting ABILIFY MAINTENA? _____

- How is ABILIFY MAINTENA given? _____
- What are the potential advantages and disadvantages of a long-acting injectable treatment?

- How could a long-acting Injectable treatment help keep my symptoms stable over the course of a month? _____
- How could ABILIFY MAINTENA help me work towards my treatment goals? _____

INDICATION AND IMPORTANT SAFETY INFORMATION for ABILIFY MAINTENA® (aripiprazole)

INDICATION

ABILIFY MAINTENA is a prescription medicine given by injection by a healthcare professional for maintenance treatment of bipolar I disorder in adults. It is not known if ABILIFY MAINTENA is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION

Elderly people with dementia-related psychosis are at increased risk of death when treated with antipsychotic medicines including ABILIFY MAINTENA. ABILIFY MAINTENA is not for the treatment of people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia).

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IMPORTANT SAFETY INFORMATION FOR ABILIFY MAINTENA® (aripiprazole) (cont'd)

Do not receive ABILIFY MAINTENA if you are allergic to aripiprazole or any of the ingredients in ABILIFY MAINTENA. Allergic reactions to aripiprazole have ranged from rash, hives and itching to anaphylaxis, which may include difficulty breathing, tightness in the chest, and swelling of the mouth, face, lips, or tongue.

ABILIFY MAINTENA may cause serious side effects including:

- **Increased risk of stroke** and ministroke has been reported in clinical studies with oral aripiprazole of elderly people with dementia-related psychosis and 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, sweating, or changes in pulse, heart rate, and blood pressure.

- **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):** 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
- feel weak or tired
- need to urinate more than usual
- feel sick to your stomach
- feel very hungry
- 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.
- **Unusual urges.** Some people receiving ABILIFY MAINTENA have had unusual urges such as gambling, binge eating or eating that you cannot control (compulsive), compulsive shopping, and sexual urges.

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.
- **Low white blood cell count**
- **Seizures (convulsions)**
- **Problems controlling your body temperature so that you feel too warm.** Do not become too hot or dehydrated while you receive 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.

• **Difficulty swallowing**

Do not drive, operate machinery, or do other dangerous activities until you know how ABILIFY MAINTENA affects you. ABILIFY MAINTENA may make you feel drowsy.

Do not drink alcohol while you receive ABILIFY MAINTENA.

Before receiving ABILIFY MAINTENA, tell your healthcare provider about all your medical conditions, including if you:

- have never taken aripiprazole before
- have diabetes or high blood sugar or a family history of diabetes or high blood sugar. Your healthcare provider should check your blood sugar before you start receiving ABILIFY MAINTENA and during your treatment.
- have or had seizures (convulsions)
- have or had low or high blood pressure
- have or had heart problems or a stroke
- have or had a low white blood cell count
- have problems that may affect you receiving an injection in your arm or buttocks
- are pregnant or plan to become pregnant. It is not known if ABILIFY MAINTENA will harm your unborn baby. 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 <http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/>
- are breastfeeding or plan to breastfeed. ABILIFY MAINTENA can pass into your milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you receive ABILIFY MAINTENA.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.

ABILIFY MAINTENA and other medicines may affect each other causing possible serious side effects. Do not start or stop any medicines during treatment with ABILIFY MAINTENA without talking to your healthcare provider first.

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

It is important to contact your healthcare provider if you experience prolonged, abnormal muscle spasms or contractions, which may be signs of a condition called dystonia.

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

If you have any questions about your health or medicines, talk to your healthcare provider.

You are encouraged to report side effects of ABILIFY MAINTENA (aripiprazole). Please contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

Please read [FULL PRESCRIBING INFORMATION](#), including **BOXED WARNING**, and [MEDICATION GUIDE](#).