



INDICATIONS:

ABILIFY MAINTENA is a prescription medicine given by injection by a healthcare professional:

- · for the treatment of schizophrenia in adults
- alone as 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:

Increased risk of death in elderly people with dementia-related psychosis. 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.

Do not receive ABILIFY MAINTENA if you are allergic to aripiprazole or any of the ingredients in ABILIFY MAINTENA.

Please read <u>IMPORTANT SAFETY INFORMATION</u> on pages 8-9.

Learn About ABILIFY MAINTENA® (aripiprazole)



Bipolar I disorder can be a lifelong condition that you manage with your healthcare provider. But it doesn't have to define who you are. If you and your healthcare provider have worked together to get your bipolar I symptoms stable, learn about a once-monthly* treatment that may help keep symptoms stable.



ABILIFY MAINTENA is the only FDA-approved once-monthly* maintenance treatment for bipolar I in adults.

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



TAKING ONE LESS PILL

Some adults with bipolar I may take a pill to manage their condition. For many, that may mean taking a pill every day. ABILIFY MAINTENA is an injection given by a healthcare provider that you receive one time each month.

Once-monthly ABILIFY MAINTENA gradually releases in your body all month long.



That means one less pill you may have to take every day for your bipolar I.[†]

[†]No medication can guarantee that you won't miss a dose. However, once you've received your once-monthly injection, the medicine is in your body being gradually released over a month.

SELECT IMPORTANT SAFETY INFORMATION:

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.

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HOW ABILIFY MAINTENA® (aripiprazole) May Help



You worked with your healthcare provider to get your bipolar I symptoms under control. ABILIFY MAINTENA is a treatment that may help keep your symptoms stable longer.* Individual results may vary.



ABILIFY MAINTENA was proven to give more time without a mood episode.*

*In a 1-year clinical trial that measured symptom control in 266 patients with bipolar I disorder, those who were treated with ABILIFY MAINTENA remained mood episode-free significantly longer than those who were on placebo.

In the same clinical trial, it was also found that:



73% of people on ABILIFY MAINTENA remained mood episode-free.[†]

[†]In the same clinical trial, significantly fewer patients had a mood episode return while on ABILIFY MAINTENA (27%) compared with those who were on placebo (51%).

UNDERSTANDING COMMON SIDE EFFECTS

As with all medications, it's important to understand the benefits and risks. The most common side effects of ABILIFY MAINTENA are:



weight gain



inner sense of restlessness (feeling like you need to move)



injection site pain



sleepiness (sedation)

■ Talk with your healthcare provider to see if ABILIFY MAINTENA is right for you.

SELECT IMPORTANT SAFETY INFORMATION:

ABILIFY MAINTENA may cause serious side effects including (continued):

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.

Please read IMPORTANT SAFETY INFORMATION on pages 8-9.

Getting Started

WITH ABILIFY MAINTENA® (aripiprazole)



Before starting treatment with ABILIFY MAINTENA, it's important to talk with your healthcare provider about past medications you've been prescribed, mood episodes you've experienced in the past year, and any side effects you may have had with your current medication.

Have you already taken the pill form of aripiprazole?



If you have taken the pill form, be sure to tell your healthcare provider. This information will help them figure out how much medicine your body will be able to tolerate when you start ABILIFY MAINTENA.



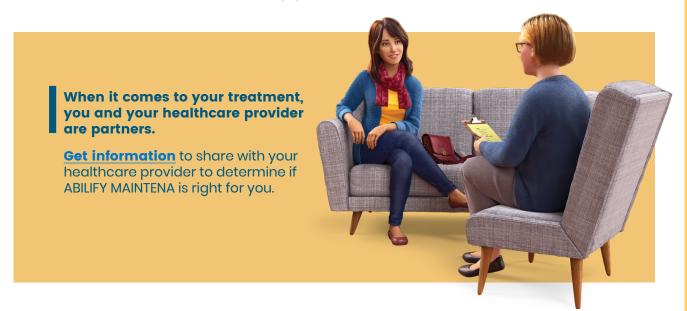
If you haven't taken the pill form, tell your healthcare provider. You will be asked to take the pill form for 2 weeks before getting your first injection of ABILIFY MAINTENA. This will help your healthcare provider determine how well your body tolerates the medicine.

SELECT IMPORTANT SAFETY INFORMATION:

ABILIFY MAINTENA may cause serious side effects including (continued):

- 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.

Please read <u>IMPORTANT SAFETY INFORMATION</u> on pages 8-9.



Getting Started

WITH ABILIFY MAINTENA® (aripiprazole) (cont'd)





Some things to keep in mind when starting ABILIFY MAINTENA:

TAKE YOUR CURRENT TREATMENT

You should keep taking your current bipolar I medication for 2 weeks after your first injection of ABILIFY MAINTENA. This allows the levels of medicine in your body to stay consistent.

KNOW WHERE TO GO

You may be able to receive ABILIFY MAINTENA:

- In your healthcare provider's office
- At a Local Care Center (LCC)* near you

THINGS TO KEEP IN MIND



RECEIVING YOUR INJECTION

You will receive your medicine in the shoulder or buttock, which may cause a little pain.

About 5% of people reported feeling injection pain.



DON'T MISS A DOSE

Following your treatment plan can help keep your mood episodes under control.



MARK YOUR INJECTION DATE

Mark your injection date on your calendar to help remember your next injection.

It's important to follow your treatment plan and stay on top of your monthly appointments. You should not miss a dose of ABILIFY MAINTENA. If you miss a dose, or experience any side effects, call your healthcare team right away to discuss what you should do next.

SELECT IMPORTANT SAFETY INFORMATION:

ABILIFY MAINTENA may cause serious side effects including (continued):

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 sick to your stomach
- feel weak or tired
 - · 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.

Please read IMPORTANT SAFETY INFORMATION on pages 8-9.

^{*}LCCs are places where you can receive your prescribed injection instead of at your healthcare provider's office. Learn more about LCCs.

Savings and Support

FOR ABILIFY MAINTENA® (aripiprazole)





FIND A LOCAL CARE CENTER NEAR YOU

There are several ways to receive your ABILIFY MAINTENA. Your healthcare provider may give you your medicine in their office, or there are also **Local Care Centers (LCCs)** available.

LCCs are places where you can get your prescribed injection instead of at your healthcare provider's office. These can be:

Retail pharmacies

Dialysis centers

Urgent care clinics

- Infusion centers
- Find a Local Care Center near you.

SELECT IMPORTANT SAFETY INFORMATION:

ABILIFY MAINTENA may cause serious side effects including (continued):

- 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
 include 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 the first few months of treatment.
- Seizures (convulsions)

Please read <u>IMPORTANT SAFETY INFORMATION</u> on pages 8-9.

Otsuka Patient Support™ offers tools and personalized patient support to help you throughout your treatment journey.

Learn more about other resources available to you.



Savings and Support

FOR ABILIFY MAINTENA® (aripiprazole) (cont'd)



You may be eligible to start saving on your ABILIFY MAINTENA prescription by taking this card to your next injection appointment.*

Eligible patients may pay as little as \$10 per 30-day calendar month with an annual maximum benefit of \$8,000 and monthly \$1,400 maximum. Presumes only 1 prescription filled per calendar month.

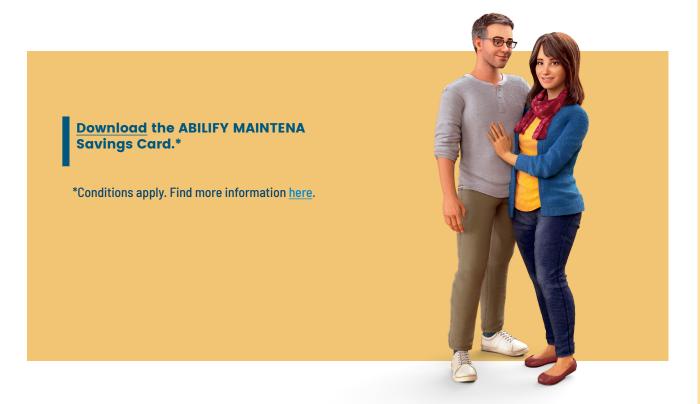


SELECT IMPORTANT SAFETY INFORMATION:

ABILIFY MAINTENA may cause serious side effects including (continued):

- Sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities. Do not drive a car, operate
 machinery, or do other dangerous activities until you know how ABILIFY MAINTENA affects you. ABILIFY MAINTENA
 may make you feel drowsy and affect your judgement, thinking, or motor skills.
- 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 that can cause food or liquid to get into your lungs.

Please read IMPORTANT SAFETY INFORMATION on pages 8-9.



INDICATIONS and IMPORTANT SAFETY INFORMATION for ABILIFY MAINTENA® (aripiprazole)

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- need to urinate more than usual
- feel weak or tired
- · 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.
- 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 include sexual
 urges, shopping, and eating or binge eating. If you or your family members notice that you are having unusual urges or
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- Low white blood cell count. Your healthcare provider may do blood tests during the first few months of treatment.
- Seizures (convulsions)
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 machinery, or do other dangerous activities until you know how ABILIFY MAINTENA affects you. ABILIFY MAINTENA
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IMPORTANT SAFETY INFORMATION for ABILIFY MAINTENA® (aripiprazole) (cont'd)

- · 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 that can cause food or liquid to get into your lungs.

Do not drink alcohol while you receive ABILIFY MAINTENA.

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

- · have never taken aripiprazole before
- have or had diabetes or high blood sugar or a family history of diabetes or high blood sugar
- have or had high levels of total cholesterol, LDL cholesterol, or triglycerides, or low levels of HDL cholesterol
- 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 or had seizures (convulsions)
- have problems that may affect you receiving an injection in your arm or buttocks
- are pregnant or plan to become pregnant. ABILIFY MAINTENA may harm your unborn baby. If you become pregnant during treatment with ABILIFY MAINTENA, talk to your healthcare provider about the risk to your unborn baby and about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or visit 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 and 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, restlessness or 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. Please contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

Please see <u>FULL PRESCRIBING INFORMATION</u>, including **BOXED WARNING**, and <u>MEDICATION GUIDE</u> for ABILIFY MAINTENA.



