

#### **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.

### **SELECT 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.





#### **SELECT IMPORTANT SAFETY INFORMATION:**

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

### **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.

# Why consider a once-monthly treatment option?

No medication can guarantee that you won't miss a dose. However, once you've received your once-monthly injection from a healthcare provider, the medicine is gradually released in your body over the course of the month. So when given each month as prescribed, ABILIFY MAINTENA® (aripiprazole) helps you avoid the need to take a daily oral medication for schizophrenia.

You should continue to take your current antipsychotic medication for 2 weeks after your first treatment with ABILIFY MAINTENA.



ABILIFY MAINTENA may help people remain relapse-free longer.† And more time without a schizophrenia relapse could mean less time focusing on symptoms.

<sup>†</sup>In a 1-year clinical study that measured symptom control in 403 patients with schizophrenia, people treated with ABILIFY MAINTENA remained relapse-free significantly longer than those who were on placebo. Relapse was defined as a return of schizophrenia symptoms.

#### **SELECT IMPORTANT SAFETY INFORMATION:**

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

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.



# **How ABILIFY MAINTENA®** (aripiprazole)

# may help

# Improving symptoms

ABILIFY MAINTENA has been shown to improve schizophrenia symptoms in patients who have experienced a relapse. Relapse was defined as a return of schizophrenia symptoms.

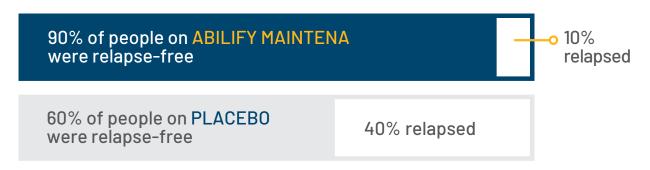


# In fact, patients given ABILIFY MAINTENA had improved symptoms in as soon as 1 week.\*

\*In a 12-week clinical study of 339 acutely relapsed patients with schizophrenia, ABILIFY MAINTENA was superior to placebo in improving schizophrenia symptoms.

# Remaining relapse-free longer

ABILIFY MAINTENA helps people with schizophrenia remain relapse-free longer.<sup>†</sup>



<sup>†</sup>In a 1-year clinical study that measured symptom control in 403 patients with schizophrenia, those who were treated with ABILIFY MAINTENA remained relapse-free significantly longer than those who were on placebo. Relapse was defined as a return of schizophrenia symptoms.

#### **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.



The most common side effects from a 12-week study of ABILIFY MAINTENA® (aripiprazole) were:



## Weight gain

- 17% of people on ABILIFY MAINTENA
- 7% of people on placebo



### **Inner sense of restlessness**

(feeling like you need to move)

- 11% of people on ABILIFY MAINTENA
- 4% of people on placebo



# **Injection site pain**

- 5% of people on ABILIFY MAINTENA
- 1% of people on placebo



# **Sleepiness**

(sedation)

- 5% of people on ABILIFY MAINTENA
- 1% of people on placebo

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

#### **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.



# Receiving ABILIFY MAINTENA® (aripiprazole)

Before starting treatment with ABILIFY MAINTENA, it's important to talk with your healthcare provider about medications you've been prescribed, relapses 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?

Remember to follow your ABILIFY MAINTENA treatment schedule exactly as your healthcare provider tells you to.



If you have taken the pill form, tell your healthcare provider so they know how your body tolerates the medicine before starting you on ABILIFY MAINTENA.



**If you haven't taken the pill form,** you will be asked to take the pill form for 2 weeks, so your healthcare provider can see how your body tolerates the medicine before starting ABILIFY MAINTENA.

When starting treatment, you will need to take ABILIFY MAINTENA along with your current medication for 2 weeks in order to maintain a consistent level of medicine in your body.

#### **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

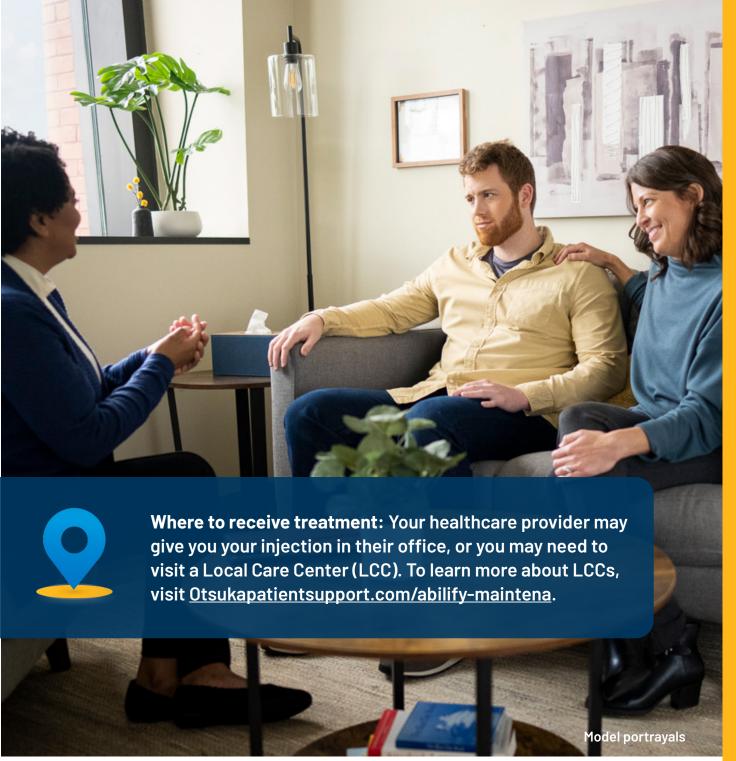
feel very hungry

feel sick to your stomach

- 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.





### **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.

# Important

# things to know about treatment



# Talk to your healthcare provider

Remember to follow your ABILIFY MAINTENA® (aripiprazole) treatment schedule exactly as your healthcare provider tells you to. 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 take ABILIFY MAINTENA with your other medicines. Do not start or stop any medicines while taking ABILIFY MAINTENA without talking to your healthcare provider first.



# Take your current treatment

You should continue to take your current schizophrenia treatment for 2 weeks after your first injection of ABILIFY MAINTENA. This allows the levels of medicine in your body to stay consistent.



# **Receiving your injection**

ABILIFY MAINTENA is given by a healthcare provider. You will receive the injection in your arm or buttock, one time every month. You may feel a little pain. About 5% of people reported feeling injection site pain.



# Don't miss a dose

If a dose is missed for some reason, call your healthcare provider right away to discuss what you should do next. Following the treatment plan may help keep relapses under control. You and your healthcare provider will determine how much medicine your body may tolerate. Mark your injection date on a calendar to help remember when the next injection appointment is.

#### **SELECT IMPORTANT SAFETY INFORMATION:**

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

- **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.







You may be eligible to start saving on your prescription with the ABILIFY MAINTENA® (aripiprazole) Savings Card. Eligible patients pay as little as \$10 per 30-day calendar month with an annual maximum benefit of \$8,000 and monthly \$1,400 maximum. This amount presumes only 1 prescription filled per calendar month.\*

\*Conditions apply. Visit ABILIFYMAINTENA.com/schizophrenia/support-coverage for full offer details.



Scan the QR code or visit

<u>ABILIFYMAINTENA.com/schizophrenia/support-coverage</u>
to learn more about savings and coverage.

#### **SELECT IMPORTANT SAFETY INFORMATION:**

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

- Low white blood cell count. Your healthcare provider may do blood tests during the first few months
  of treatment.
- Seizures (convulsions)
- 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.





### **SELECT IMPORTANT SAFETY INFORMATION:**

• **Difficulty swallowing** that can cause food or liquid to get into your lungs. **Do not** drink alcohol while you receive ABILIFY MAINTENA.

# Mental health resources

Finding support in the community doesn't have to be difficult. Here are just some of the many resources and organizations doing important work through community building, research, and advocacy:



### The National Alliance on Mental Illness (NAMI)

Provides advocacy, education, support, and public awareness to help those affected by mental illness.



### **Clubhouse International**

Helps people living with mental illness around the world regain a respected place in society through work, education, wellness, and community.

The organizations and resources listed are not affiliated with nor are they controlled or influenced by Otsuka America Pharmaceutical, Inc. (OAPI) and Lundbeck. OAPI or Lundbeck may have entered into limited fee-for-service arrangements with some of the listed organizations and resources from time to time. OAPI and Lundbeck are providing information to you about these organizations and resources merely as a convenience, and OAPI and Lundbeck shall not be liable for any use of this information, or for any information obtained from or provided by these organizations or resources. OAPI and Lundbeck are not responsible for the consequences of your use of any information provided by these organizations and resources.

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

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

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

· feel very thirsty

- feel very hungry
- need to urinate more than usual
- 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.
- 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)

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

- 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.

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 (<a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>).

Please see FULL PRESCRIBING INFORMATION, including BOXED WARNING, and MEDICATION GUIDE for ABILIFY MAINTENA.



# Learn more about





Scan the OR Code or visit ABILIFYMAINTENA.com/schizophrenia to learn more about ABILIFY MAINTENA

Please see FULL PRESCRIBING INFORMATION, including BOXED WARNING, and MEDICATION GUIDE for ABILIFY MAINTENA.

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