

If you're treating bipolar I disorder with a daily pill:

What's stopping you from moving to a long-acting injectable (LAI)?

See inside for answers to some questions you may have



ABILIFY ASIMTUFII® (aripiprazole) is used alone as a maintenance treatment for bipolar I disorder for adults.

SELECT IMPORTANT SAFETY INFORMATION

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

ABILIFY ASIMTUFII and ABILIFY MAINTENA® (aripiprazole) increase the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). ABILIFY ASIMTUFII and ABILIFY MAINTENA are not for the treatment of people with dementia-related psychosis.

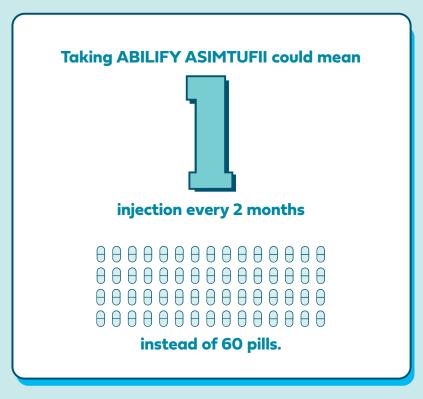
What is a long-acting injectable (LAI)



A potential alternative to taking a daily maintenance pill for bipolar I disorder

- LAIs are injections given by a healthcare professional
- They use the same medicine that comes in a pill form—the medicine is released in your body over time

ABILIFY ASIMTUFII® (aripiprazole) is an LAI given once every 2 months.



Work with your healthcare provider to make sure you can tolerate aripiprazole prior to starting treatment.

SELECT IMPORTANT SAFETY INFORMATION

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

ABILIFY ASIMTUFII or 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.



Will the ABILIFY ASIMTUFII injection hurt



In a study of ABILIFY ASIMTUFII*:



Most people did not feel pain

About 4 out of 5 people receiving ABILIFY ASIMTUFII did not report feeling injection site pain.



Pain was low

On average, people in the study who reported feeling pain rated their pain as less than 4 on a scale from 0 to 100.

Most people who said they felt injection site pain reported that the pain lessened with each injection after that.



About the injection

You'll receive the ABILIFY ASIMTUFII injection just below your waistline in the upper gluteal muscle.

You may need to loosen a belt or a waistband, but there typically is no need to remove clothing.

Ready to learn more?
Click here to watch a video about LAIs.

*A study of 266 adults with schizophrenia or bipolar disorder evaluated the side effects of ABILIFY ASIMTUFII 960 mg and ABILIFY MAINTENA 400 mg.

SELECT IMPORTANT SAFETY INFORMATION

ABILIFY ASIMTUFII or 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 signs and symptoms of NMS: high fever, confusion, changes
in pulse, heart rate, and blood pressure, stiff muscles, and increased sweating.



How will I know if ABILIFY ASIMTUFII is right for me



Your doctor will make sure your body can tolerate aripiprazole prior to starting treatment

ABILIFY ASIMTUFII is an LAI that uses the medicine aripiprazole. Aripiprazole is the same medicine that's used in ABILIFY® (aripiprazole) tablets.*



If you are already taking aripiprazole tablets or have taken them in the past:

Your doctor may have you keep taking them for up to 2 weeks after your first injection.



If you haven't taken aripiprazole tablets in the past:

Your doctor may start you on them for up to 2 weeks to see how you feel before you start on ABILIFY ASIMTUFII.

Talk to your doctor about how to move to ABILIFY ASIMTUFII from your current medication.

*ABILIFY tablets are indicated for the treatment of manic or mixed episodes associated with bipolar I disorder in adults and in pediatric patients 10 to 17 years of age.

SELECT IMPORTANT SAFETY INFORMATION

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

 Uncontrolled body movements (tardive dyskinesia). ABILIFY ASIMTUFII and 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 ASIMTUFII or ABILIFY MAINTENA. Tardive dyskinesia may also start after you stop receiving ABILIFY ASIMTUFII or ABILIFY MAINTENA.



Where will I go for treatment?

Options for where you can receive ABILIFY ASIMTUFII







There are several types of locations where you may be able to get your ABILIFY ASIMTUFII injections. Some retail pharmacies and clinics serve as Local Care Centers (LCCs) that give LAI injections.

Ready to save on your prescription?

<u>Click here</u> to learn about the Savings Card.

SELECT IMPORTANT SAFETY INFORMATION

ABILIFY ASIMTUFII or 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 are treated with ABILIFY ASIMTUFII or ABILIFY MAINTENA® (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 treatment with ABILIFY ASIMTUFII or ABILIFY MAINTENA, and during treatment.

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

INDICATIONS:

ABILIFY ASIMTUFII 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

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 ASIMTUFII or 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 ASIMTUFII and ABILIFY MAINTENA increase the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). ABILIFY ASIMTUFII and ABILIFY MAINTENA are not for the treatment of people with dementia-related psychosis.

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

ABILIFY ASIMTUFII or 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 signs and symptoms of NMS: high fever, confusion, changes in pulse, heart rate, and blood pressure, stiff muscles, and increased sweating.
- Uncontrolled body movements (tardive dyskinesia). ABILIFY ASIMTUFII and 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 ASIMTUFII or ABILIFY MAINTENA. Tardive dyskinesia may also start after you stop receiving ABILIFY ASIMTUFII or ABILIFY MAINTENA.
- · Problems with your metabolism such as:
 - » High blood sugar (hyperglycemia) and diabetes: Increases in blood sugar can happen in some people who are treated with ABILIFY ASIMTUFII or 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 treatment with ABILIFY ASIMTUFII or ABILIFY MAINTENA, and during treatment.

Call your healthcare provider if you have any of these symptoms of high blood sugar during treatment with ABILIFY ASIMTUFII or 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.
- Unusual and uncontrollable (compulsive) urges. Some people receiving ABILIFY ASIMTUFII or 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.



IMPORTANT SAFETY INFORMATION for ABILIFY ASIMTUFII® (aripiprazole) and ABILIFY MAINTENA® (aripiprazole) (continued)

- Falls. ABILIFY ASIMTUFII and 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)
- 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 ASIMTUFII
 or ABILIFY MAINTENA affects you. ABILIFY ASIMTUFII or 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 during treatment with ABILIFY ASIMTUFII or 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 during treatment with ABILIFY ASIMTUFII or ABILIFY MAINTENA.

Before receiving ABILIFY ASIMTUFII or ABILIFY MAINTENA, tell your healthcare provider about all 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 buttocks (ABILIFY ASIMTUFII and ABILIFY MAINTENA) or arm (ABILIFY MAINTENA)
- are pregnant or plan to become pregnant. ABILIFY ASIMTUFII or ABILIFY MAINTENA may
 harm your unborn baby. If you become pregnant during treatment with ABILIFY ASIMTUFII or
 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 ASIMTUFII or 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 ASIMTUFII or 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 ASIMTUFII or 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 ASIMTUFII or ABILIFY MAINTENA without talking to your healthcare provider first.

The most common side effects of ABILIFY ASIMTUFII or 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 ASIMTUFII or 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 ASIMTUFII and 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 accompanying FULL PRESCRIBING INFORMATION, including **BOXED WARNING**, for <u>ABILIFY ASIMTUFII</u> and <u>ABILIFY MAINTENA</u>, and MEDICATION GUIDE for ABILIFY ASIMTUFII and ABILIFY MAINTENA.





It's important to talk with your healthcare provider about your treatment. We understand, it's not always easy to know what to ask.

Here are some questions to help you start the conversation:

Could	ABILIFY ASIMTUFII® (aripiprazole) help control my bipolar I disorder symptoms?
Are th	ne side effects similar to my current treatment?
	Where will I go for my injection?
Click her	e to create a personalized Doctor Discussion Guide.

Talk to your doctor about ABILIFY ASIMTUFII for long-lasting symptom control.*

*Based on a 1-year study of people treated with once-monthly ABILIFY MAINTENA $^{ ext{@}}$ (aripiprazole), people treated with ABILIFY MAINTENA had no mood episodes for a significantly longer time than those on placebo. In a separate 8-month study of ABILIFY ASIMTUFII and ABILIFY MAINTENA in patients with bipolar I disorder and schizophrenia, it was shown that both medicines resulted in similar levels of aripiprazole in the body, suggesting a similar level of symptom control. Results may vary.

SELECT IMPORTANT SAFETY INFORMATION

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

- Problems with your metabolism such as (continued): Call your healthcare provider if you have any of these symptoms of high blood sugar
 - during treatment with ABILIFY ASIMTUFII or 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.
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