

# Long-lasting symptom control\* may be possible with 1 treatment every-2-months.†

Learn about ABILIFY ASIMTUFII® (aripiprazole), the only once every-2-months maintenance treatment for bipolar I disorder in adults.

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



\*Based on a 1-year study of once-monthly ABILIFY MAINTENA® (aripiprazole), 400 mg extended-release injectable suspension, people treated with ABILIFY MAINTENA remained mood episode-free significantly longer than those on placebo. Results may vary.

†Based on a separate study of ABILIFY ASIMTUFII and ABILIFY MAINTENA, both medicines resulted in similar levels of aripiprazole in the body, suggesting a similar level of symptom control.



## INDICATIONS:

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

- alone as maintenance treatment of bipolar I disorder in adults

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

- 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.

## SELECT 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.

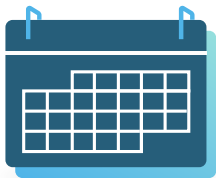
Please read [IMPORTANT SAFETY INFORMATION](#) on pages 9-10.



## A once every-2-months treatment option

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

2 Months



**ABILIFY ASIMTUFII® (aripiprazole) is the only FDA-approved maintenance treatment for bipolar I disorder in adults that may provide 2 months of symptom control with 1 dose.**

ABILIFY ASIMTUFII (a-BIL-i-fy AH-SIM-TUH-FYE) 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 ASIMTUFII is safe and effective in children under 18 years of age.

### 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.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 9-10.



# How ABILIFY ASIMTUFII® (aripiprazole) may help give you long-lasting symptom control

ABILIFY ASIMTUFII is approved by the FDA as a maintenance treatment for bipolar I disorder in adults based in part on 2 studies:

In the first, a 1-year study of ABILIFY MAINTENA® (aripiprazole), a once-monthly treatment\* for people living with bipolar I disorder, it was found that:

**Significantly fewer patients had a mood episode return** while on ABILIFY MAINTENA. **That means you may stay mood episode-free longer.** And more time without a relapse could mean less time focusing on symptoms. Individual results may vary.

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

In the second, an 8-month study of ABILIFY ASIMTUFII and ABILIFY MAINTENA in patients with bipolar I disorder and schizophrenia, it was shown that:

The medicine in ABILIFY ASIMTUFII **stayed at a similar level** in the body as the medicine in ABILIFY MAINTENA **for 2 months.**

## 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.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 9-10.

Visit [AbilifyAsimtufii.com/BPI/DiscussionGuide](https://AbilifyAsimtufii.com/BPI/DiscussionGuide) to create a discussion guide that can help you talk to your healthcare provider to see if ABILIFY ASIMTUFII® (aripiprazole) is right for you.



## COMMON SIDE EFFECTS

The safety profile of ABILIFY ASIMTUFII is based on the safety profile of ABILIFY MAINTENA® (aripiprazole). In a 12-week clinical trial, the most common side effects of ABILIFY MAINTENA were:



Weight gain



Injection site pain



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



Sleepiness (sedation)

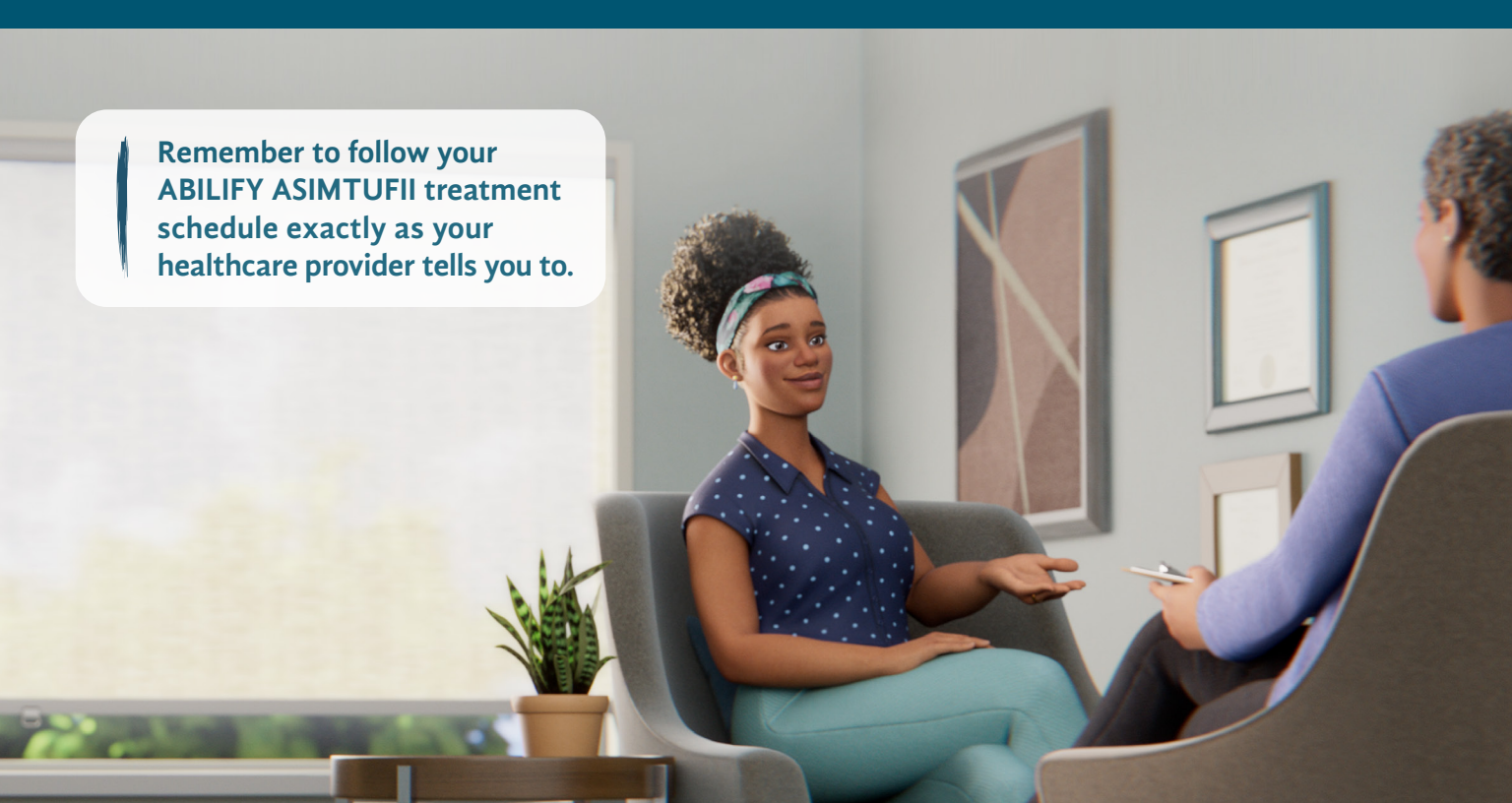
These are not all the possible side effects.

## 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.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 9-10.



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

## Receiving ABILIFY ASIMTUFII® (aripiprazole)

ABILIFY ASIMTUFII is an injection given by a healthcare provider in the buttock once every 2 months.

Before starting treatment with ABILIFY ASIMTUFII, it's important to talk with your healthcare provider about all of your medical conditions, all of the past medications you've been prescribed, and all of the medications you currently take.

**If you are taking the pill form of aripiprazole**, tell your healthcare provider so they know how your body tolerates the medicine before starting you on ABILIFY ASIMTUFII. After your first injection, continue to take oral aripiprazole for 2 weeks. Then, ABILIFY ASIMTUFII will be given once every 2 months.

**If you are receiving ABILIFY MAINTENA® (aripiprazole)**, ABILIFY ASIMTUFII can be given in place of the next scheduled injection of ABILIFY MAINTENA and should be given once every 2 months. Your healthcare provider will let you know when that time comes.

If you haven't previously taken the pill form of aripiprazole, talk to your healthcare provider.

### 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. 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.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 9-10.

# Important things to keep in mind



## Talk to your healthcare provider

Remember to follow your ABILIFY ASIMTUFII® (aripiprazole) treatment schedule exactly as your healthcare provider tells you to. Your healthcare provider can tell you if it is safe to take ABILIFY ASIMTUFII with your other medicines. Do not start or stop any medicines while taking ABILIFY ASIMTUFII without talking to your healthcare provider first.



## Take your current treatment

If you're taking an oral antipsychotic, you should continue to take this medication for 2 weeks after your first injection of ABILIFY ASIMTUFII.



## Receiving your injection

ABILIFY ASIMTUFII is an injection given by a healthcare provider in your buttock. You may feel a little pain during the injection. In one clinical study, about 1 in 5 people using ABILIFY ASIMTUFII reported feeling injection site pain versus about 1 in 10 people using ABILIFY MAINTENA® (aripiprazole). Most people who reported feeling injection site pain reported that the pain lessened with each injection.



## Don't miss a dose

Mark your injection date on a calendar to help you remember when your next injection appointment is. If you miss a dose for some reason, call your healthcare provider right away to discuss what you should do next.



## Know where to go

Your healthcare provider may give you your ABILIFY ASIMTUFII injection in their office, or you can find a Local Care Center (LCC) in your area.

LCCs can be retail pharmacies, urgent care clinics, dialysis centers, or infusion centers where a healthcare provider is available to give you your ABILIFY ASIMTUFII injection.

To find a Local Care Center near you, visit [OtsukaPatientSupport.com/abilify-asimtufii](https://OtsukaPatientSupport.com/abilify-asimtufii).

### **ABILIFY ASIMTUFII and other medicines may affect each other, causing possible serious side effects.**

ABILIFY ASIMTUFII may affect the way other medicines work, and other medicines may affect how ABILIFY ASIMTUFII works. Your healthcare provider can tell you if it is safe to take ABILIFY ASIMTUFII with your other medicines.

## SELECT IMPORTANT SAFETY INFORMATION

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
- 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

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 9-10.

Discover all the resources available to you at [AbilifyAsimtufii.com/BPI/Resources](https://AbilifyAsimtufii.com/BPI/Resources).



# Saving on your treatment



You may be eligible to start saving on your prescription with the ABILIFY ASIMTUFII® (aripiprazole) Savings Card.\* Eligible patients may pay as little as \$5 per fill with an annual maximum benefit of \$8,000 and a monthly maximum benefit of wholesale acquisition cost plus usual and customary pharmacy charges. Presumes only 1 prescription filled per 2 calendar months.

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

\*Conditions apply. For more information, visit [AbilifyAsimtufiiSavingsCard.com](https://AbilifyAsimtufiiSavingsCard.com).



Scan the QR code or visit [AbilifyAsimtufii.com/BPI/Savings](https://AbilifyAsimtufii.com/BPI/Savings) to learn more about savings and coverage.

## SELECT IMPORTANT SAFETY INFORMATION

Call your healthcare provider if you have any of these symptoms of high blood sugar during treatment with ABILIFY ASIMTUFII or ABILIFY MAINTENA® (aripiprazole) (continued):

- » **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 9-10.

# Support from the mental health community

Having the right support can help you along your journey living with bipolar I disorder. This page can help you find national and local support groups as well as other tools and resources to help you stay on track.



## [My Mental Health Crisis Plan App](#)

Designed to help empower and guide your treatment preferences during a mental health crisis.



## [The National Alliance on Mental Illness \(NAMI\)](#)

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



## [Depression and Bipolar Support Alliance \(DBSA\)](#)

Provides in-person and online peer support dedicated to improving the lives of people living with mood disorders.

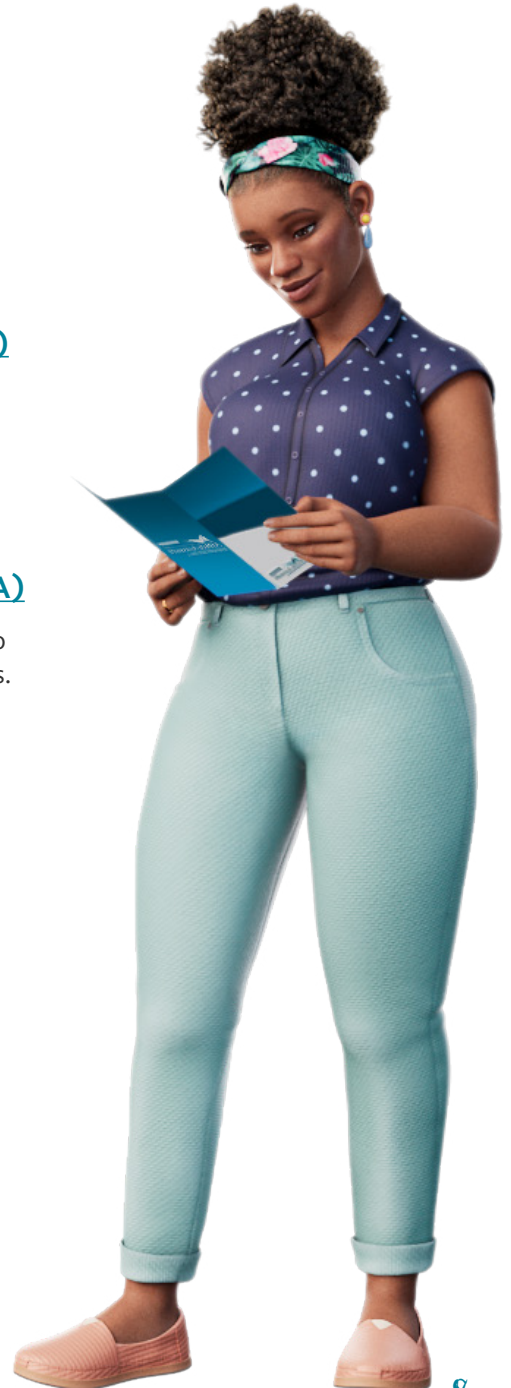


## [Clubhouse International](#)

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.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 9-10.





# 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:

- alone as maintenance treatment of bipolar I disorder in adults

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

- 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.
- **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.

Please see FULL PRESCRIBING INFORMATION, including **BOXED WARNING** and MEDICATION GUIDE for [ABILIFY ASIMTUFII](#) and [ABILIFY MAINTENA](#).

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

- **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 judgment, 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. Your healthcare provider should check your blood sugar before you start receiving ABILIFY ASIMTUFII or ABILIFY MAINTENA and during your treatment.
- 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 medicine 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](http://www.fda.gov/medwatch)).

# Learn more about



Scan the QR code or visit  
[AbilifyAsimtufii.com](https://AbilifyAsimtufii.com) to learn more.

## INDICATIONS:

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