

Starting the conversation about a once every-2-months* treatment option



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



Here is your customized discussion guide. Bring it to your next appointment to help you and your healthcare provider determine if once every-2-months ABILIFY ASIMTUFII® (aripiprazole) is right for you.

INDICATION and IMPORTANT SAFETY INFORMATION for ABILIFY ASIMTUFII 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.

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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) (CONTINUED)

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.
- **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. 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)

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

- 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)

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