

MEDICATION GUIDE
ABILIFY ASIMTUFII® (a-BIL-i-fy AH-SIM-TUH-FYE)
(aripiprazole) for extended-release injectable suspension, for intramuscular use

What is the most important information I should know about ABILIFY ASIMTUFII?

ABILIFY ASIMTUFII may cause serious side effects, including:

- **Increased risk of death in elderly people with dementia-related psychosis.** ABILIFY ASIMTUFII increases the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). ABILIFY ASIMTUFII is not for the treatment of people with dementia-related psychosis.

What is ABILIFY ASIMTUFII?

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

- for the treatment of schizophrenia in adults
- alone as 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.

Do not receive ABILIFY ASIMTUFII if you are allergic to aripiprazole or any of the ingredients in ABILIFY ASIMTUFII. See the end of this Medication Guide for a complete list of ingredients in ABILIFY ASIMTUFII.

Before receiving ABILIFY ASIMTUFII, 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. Your healthcare provider should check your blood sugar before you start receiving ABILIFY ASIMTUFII and during your treatment with ABILIFY ASIMTUFII.
- 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
- are pregnant or plan to become pregnant. ABILIFY ASIMTUFII may harm your unborn baby. Receiving ABILIFY ASIMTUFII during your third trimester of pregnancy may cause your baby to have abnormal muscle movements or withdrawal symptoms after birth. Talk to your healthcare provider about the risk to your unborn baby if you receive ABILIFY ASIMTUFII during pregnancy.
 - Tell your healthcare provider right away if you become pregnant or think that you are pregnant during treatment with ABILIFY ASIMTUFII.
 - If you become pregnant during treatment with ABILIFY ASIMTUFII, talk to your healthcare provider 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 can pass into your breast milk and it is not known if it may harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with ABILIFY ASIMTUFII.

Tell your healthcare provider about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements.

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 receive ABILIFY ASIMTUFII with your other medicines. Do not start or stop any medicines during treatment with ABILIFY ASIMTUFII without first talking to your healthcare provider.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I receive ABILIFY ASIMTUFII?

- Follow your ABILIFY ASIMTUFII treatment schedule exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much ABILIFY ASIMTUFII you will receive and when you will receive it.
- ABILIFY ASIMTUFII is an injection given only in your buttock by your healthcare provider 1 time every 2 months.

- After your first injection of ABILIFY ASIMTUFII, you should continue to take your current antipsychotic medicine by mouth for 2 weeks.
- You should not miss a dose of ABILIFY ASIMTUFII. If you miss a dose for some reason, call your healthcare provider right away to discuss what you should do next.

What should I avoid while receiving ABILIFY ASIMTUFII?

- **Do not** drive a car, operate machinery, or do other dangerous activities until you know how ABILIFY ASIMTUFII affects you. ABILIFY ASIMTUFII may affect your judgement, thinking or motor skills.
- **Do not** drink alcohol during treatment with ABILIFY ASIMTUFII.
- **Do not** become too hot or dehydrated during treatment with ABILIFY ASIMTUFII.
 - **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.

What are the possible side effects of ABILIFY ASIMTUFII?

ABILIFY ASIMTUFII may cause serious side effects, including:

- See "**What is the most important information I should know about ABILIFY ASIMTUFII?**"
- **Stroke, (cerebrovascular problems) in elderly people with dementia-related psychosis that 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
 - increased sweating
- **Uncontrolled body movements (tardive dyskinesia).** ABILIFY ASIMTUFII 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. Tardive dyskinesia may also start after you stop receiving ABILIFY ASIMTUFII.
- **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. 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, and during treatment with ABILIFY ASIMTUFII.

Call your healthcare provider if you have any of these symptoms of high blood sugar during treatment with ABILIFY ASIMTUFII:

 - 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 with ABILIFY ASIMTUFII.
- **Unusual and uncontrollable (compulsive) urges.** Some people receiving ABILIFY ASIMTUFII have had unusual strong urges to gamble and gambling that cannot be controlled (compulsive gambling). Other compulsive urges including 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 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 your first few months of treatment with ABILIFY ASIMTUFII.
- **Seizures (convulsions)**
- **Sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities.** See "What should I avoid while receiving ABILIFY ASIMTUFII?"
- **Problems controlling your body temperature so that you feel too warm.** See "What should I avoid while receiving ABILIFY ASIMTUFII?"
- **Difficulty swallowing** that can cause food or liquid to get into your lungs.

The most common side effects of ABILIFY ASIMTUFII include: weight gain, restlessness or feeling like you need to move (akathisia), injection site pain, or sleepiness (sedation).

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of ABILIFY ASIMTUFII.

If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about ABILIFY ASIMTUFII that is written for healthcare professionals.

What are the ingredients in ABILIFY ASIMTUFII?

Active ingredient: aripiprazole monohydrate

Inactive ingredients: carboxymethylcellulose sodium, polyethylene glycol 400, povidone, sodium chloride, sodium phosphate monobasic monohydrate, sodium hydroxide and water for injection.

ABILIFY ASIMTUFII is a trademark of Otsuka Pharmaceutical Co., Ltd.

© 2023, Otsuka Pharmaceutical Co., Ltd., 2-9 Kanda-Tsukasamachi, Chiyoda-ku, Tokyo, 101-8535 Japan

For more information about ABILIFY ASIMTUFII, go to www.ABILIFY.com or call 1-800-441-6763.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued: 4/2023

23US23IBR0002