

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

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

