

MEDICATION GUIDE
ARISTADA[®] (air-is-TAH-dah)
(aripiprazole lauroxil)

extended-release injectable suspension, for intramuscular use

What is the most important information I should know about ARISTADA?

Each injection of ARISTADA must be administered by a healthcare professional only.

ARISTADA may cause serious side effects, including:

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

What is ARISTADA?

ARISTADA is a prescription medicine used to treat schizophrenia in adults.

It is not known if ARISTADA is safe and effective in children under 18 years of age.

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

See the end of this Medication Guide for a complete list of ingredients in ARISTADA.

Before receiving ARISTADA, tell your healthcare provider about all of your medical conditions, including if you:

- have never taken ABILIFY[®], ABILIFY MAINTENA[®] or any aripiprazole product before
- have or had heart problems or a stroke
- have 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 ARISTADA and during your treatment.
- have or had low or high blood pressure
- have or had seizures (convulsions)
- have or had a low white blood cell count
- have problems that may affect you receiving an injection in your buttocks or your arm
- are pregnant or plan to become pregnant. It is not known if ARISTADA will harm your unborn baby.
 - If you become pregnant while receiving ARISTADA, 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. ARISTADA 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 if you receive ARISTADA.

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

ARISTADA and other medicines may affect each other causing possible serious side effects.

ARISTADA may affect the way other medicines work, and other medicines may affect how ARISTADA works.

Your healthcare provider can tell you if it is safe to receive ARISTADA with your other medicines. Do not start or stop any medicines while receiving ARISTADA without talking to your healthcare provider first.

How should I receive ARISTADA?

- Follow your ARISTADA treatment schedule exactly as your healthcare provider tells you to.
- Each ARISTADA is an injection given by your healthcare provider into the muscle (intramuscular) of your arm or buttock.
- There are 2 ways to start treatment with ARISTADA:
 - **Option 1:** You will receive **1** dose of ARISTADA INITIO in combination with a single dose of oral aripiprazole. You may also receive your first injection of ARISTADA on the same day you receive ARISTADA INITIO or up to 10 days after you receive ARISTADA INITIO.
 - **Option 2:** After your first injection of ARISTADA, you will take oral aripiprazole for **21** days in a row (consecutive).
- You should not miss a dose of ARISTADA. 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 ARISTADA?

- **Do not** drive a car, operate hazardous machinery, or do other dangerous activities until you know how ARISTADA affects you. ARISTADA may affect your judgment, thinking or motor skills.
- **Avoid** becoming too hot or dehydrated while you receive ARISTADA.
 - **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 ARISTADA?

ARISTADA may cause serious side effects, including:

- See “**What is the most important information I should know about ARISTADA?**”
- **Cerebrovascular problems (including stroke) 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 hospital emergency room right away if you have some or all of the following signs symptoms of NMS:
 - high fever
 - sweating
 - stiff muscles
 - changes in pulse, heart rate and blood pressure
 - confusion
- **Uncontrolled body movements (tardive dyskinesia).** ARISTADA 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 ARISTADA. Tardive dyskinesia may also start after you stop receiving ARISTADA.
- **Problems with your metabolism such as:**
 - **high blood sugar (hyperglycemia).** Increases in blood sugar can happen in some people who receive ARISTADA. 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 receiving ARISTADA and during your treatment.
Call your healthcare provider if you have any of these symptoms of high blood sugar while receiving ARISTADA:
 - 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.
- **Unusual and uncontrollable (compulsive) urges.** Some people taking aripiprazole products have had strong unusual urges to gamble and gambling that cannot be controlled (compulsive gambling). Other compulsive urges include increased sexual urges, shopping, and eating or binge eating. If you or your family members notice that you are having unusual urges, 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.** ARISTADA may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position 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**
- **Seizures (convulsions)**
- **Problems controlling your body temperature. See “What should I avoid while receiving ARISTADA?”**
- **Difficulty swallowing**

The most common side effects of ARISTADA include restlessness or feeling like you need to move (akathisia).

These are not all the possible side effects of ARISTADA.

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

General information about ARISTADA

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

What are the ingredients in ARISTADA?

Active ingredient: aripiprazole lauroxil

Inactive ingredients: sorbitan monolaurate, polysorbate 20, sodium chloride, sodium phosphate dibasic anhydrous, sodium phosphate monobasic and water for injection

Manufactured and marketed by: Alkermes, Inc., 852 Winter Street, Waltham, MA 02451-1420
For more information, go to www.ARISTADA.com or call 1-866-274-7823.

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

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