

MEDICATION GUIDE
ARISTADA INITIO® (air-is-TAH-dah i-ni'-she-oh)
(aripiprazole lauroxil)
extended-release injectable suspension, for intramuscular use

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

ARISTADA INITIO may cause serious side effects, including:

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

What is ARISTADA INITIO?

ARISTADA INITIO is a prescription medicine given as a **one-time injection** and is used in combination with oral aripiprazole to start ARISTADA treatment, or re-start ARISTADA treatment after a missed dose, when ARISTADA is used for the treatment of schizophrenia in adults.

It is not known if ARISTADA INITIO is safe and effective in children.

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

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

- have not 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 receive ARISTADA INITIO.
- have or had low or high blood pressure
- have or had seizures (convulsions)
- have or had a low white blood cell count
- are pregnant or plan to become pregnant. It is not known if ARISTADA INITIO will harm your unborn baby.
 - If you become pregnant after you receive ARISTADA INITIO, 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 INITIO 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 after you receive ARISTADA INITIO.

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

ARISTADA INITIO and other medicines may affect each other causing possible serious side effects. ARISTADA INITIO may affect the way other medicines work, and other medicines may affect how ARISTADA INITIO works.

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

How will I receive ARISTADA INITIO?

- Follow your ARISTADA INITIO treatment schedule exactly as your healthcare provider tells you to.
- ARISTADA INITIO is a **one-time injection** given by your healthcare provider, into the muscle (intramuscular) of your arm or buttock.
- ARISTADA INITIO is given 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.
- ARISTADA INITIO should only be used as a one-time dose to start ARISTADA treatment or to re-start ARISTADA treatment after a missed dose. ARISTADA INITIO is not meant for repeated dosing.

What should I avoid after I receive ARISTADA INITIO?

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

ARISTADA INITIO may cause serious side effects, including:

- See “What is the most important information I should know about ARISTADA INITIO?”
- **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 and symptoms of NMS:
 - high fever
 - stiff muscles
 - confusion
 - sweating
 - changes in pulse, heart rate, and blood pressure
- **Uncontrolled body movements (tardive dyskinesia).** ARISTADA INITIO may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away.
- **Problems with your metabolism such as:**
 - **high blood sugar (hyperglycemia).** Increases in blood sugar can happen in some people who receive ARISTADA INITIO. 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 receive ARISTADA INITIO.

Call your healthcare provider if you have any of these symptoms of high blood sugar:

 - 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.**
- **Unusual and uncontrollable (compulsive) urges.** Some people taking aripiprazole have had strong unusual 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 strong 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 INITIO 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 after I receive ARISTADA INITIO?”
- **Difficulty swallowing**

The most common side effects of ARISTADA INITIO include restlessness or feeling like you need to move (akathisia). These are not all the possible side effects of ARISTADA INITIO.

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 INITIO

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

What are the ingredients in ARISTADA INITIO?

Active ingredient: aripiprazole lauroxil

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

Manufactured and marketed by: Alkermes, Inc., Waltham, MA 02451

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

Revised 12/2023