

INDICATION and IMPORTANT SAFETY INFORMATION for ARISTADA® (aripiprazole lauroxil) extended-release injectable suspension, for intramuscular use

INDICATION

ARISTADA is a prescription medicine given by injection by a healthcare professional and used to treat schizophrenia. It is not known if ARISTADA is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION

Elderly people with dementia-related psychosis are at increased risk of death when treated with antipsychotic medicines including ARISTADA. ARISTADA is not for the treatment of people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia).

Contraindication: Do not receive ARISTADA if you are allergic to aripiprazole or any of the ingredients in ARISTADA. Allergic reactions to aripiprazole have ranged from rash, hives and itching to anaphylaxis, which may include difficulty breathing, tightness in the chest, and swelling of the mouth, face, lips, or tongue.

ARISTADA may cause serious side effects including:

- **Stroke (cerebrovascular problems) in elderly people that can lead to death.**
- **Neuroleptic malignant syndrome (NMS), a rare and serious condition that can lead to death. Call your healthcare provider right away** if you have some or all of the following symptoms of NMS:
 - high fever
 - stiff muscles
 - confusion
 - sweating
 - changes in pulse, heart rate, and blood pressure
- **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.
- **Gambling urges and other uncontrollable (compulsive) behaviors.** There is the possibility that you may have strong urges to gamble, shop, have sex, binge eat or have other uncontrollable strong urges. If you or your family members notice that you are having uncontrollable 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.** Because antipsychotic medicines like ARISTADA may cause drowsiness or dizziness when standing, you may be at risk for falls and related injuries.
- **Low white blood cell count**
- **Seizures (convulsions)**
- **Problems controlling your body temperature so that you feel too warm.** **Do not** become 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.
- **Difficulty swallowing**

The most common side effect of ARISTADA includes feeling like you need to move to stop unpleasant feelings in your legs (restless leg syndrome or akathisia). These are not all the possible side effects of ARISTADA. Tell your healthcare provider if you have any side effect that bothers you or does not go away.

Do not drive, operate machinery, or do other dangerous activities until you know how ARISTADA affects you. ARISTADA may make you feel drowsy.

Do not drink alcohol while you receive 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 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 seizures (convulsions)
- 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 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 taking 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. 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. Do not start or stop any medicines while receiving ARISTADA without talking to your healthcare provider first.

If you have any questions about your health or medicines, talk to your healthcare provider.

You are encouraged to report all side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

[Please see full Prescribing Information, including Boxed Warning, and Medication Guide.](#)

ARISTADA®
aripiprazole lauroxil
extended-release injectable suspension
441 mg • 662 mg • 882 mg • 1064 mg



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