

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

INDICATION

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.

ARISTADA is a prescription medicine given by injection by a healthcare professional and used to treat schizophrenia.

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

IMPORTANT SAFETY INFORMATION

Elderly people with dementia-related psychosis are at increased risk of death when treated with antipsychotic medicines including ARISTADA INITIO and ARISTADA. ARISTADA INITIO and ARISTADA are 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 INITIO or 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 INITIO and/or ARISTADA may cause serious side effects including:

- **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:
 - o high fever
 - o stiff muscles
 - o confusion
 - o sweating
 - o changes in pulse, heart rate, and blood pressure
- **Uncontrolled body movements (tardive dyskinesia).** ARISTADA INITIO and 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:

- o **High blood sugar (hyperglycemia).** Increases in blood sugar can happen in some people who receive ARISTADA INITIO and/or 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 receive ARISTADA INITIO and/or ARISTADA and during your treatment with ARISTADA.

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

- 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

- o **Increased fat levels (cholesterol and triglycerides) in your blood**

- o **Weight gain.** You and your healthcare provider should check your weight regularly.

• Unusual and uncontrollable (compulsive) urges.

Some people taking aripiprazole have had strong unusual urges such as 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 and ARISTADA may make you sleepy or dizzy when standing which may make you 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 INITIO and/or 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 effects of ARISTADA INITIO and ARISTADA include restlessness or feeling like you need to move (akathisia). These are not all the possible side effects of ARISTADA INITIO and ARISTADA. You should tell your healthcare provider about any side-effects you have.

Do not drive, operate hazardous machinery, or do other dangerous activities until you know how ARISTADA INITIO and ARISTADA affect you. ARISTADA INITIO and ARISTADA may affect your judgment, thinking or motor skills.

Before receiving ARISTADA INITIO and ARISTADA 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 and/or ARISTADA and during your treatment with ARISTADA
- 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 INITIO and/or ARISTADA will harm your unborn baby. If you become pregnant while taking ARISTADA INITIO and/or 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 INITIO and/or 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 INITIO and/or ARISTADA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ARISTADA INITIO and ARISTADA and other medicines may affect each other causing possible serious side effects. Do not start or stop any medicines after you receive ARISTADA INITIO and 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 for ARISTADA INITIO and ARISTADA, including Boxed Warning, and Medication Guides for ARISTADA INITIO and ARISTADA.



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ARISTADA
INITIO™
aripiprazole lauroxil
extended-release injectable suspension
675 mg

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