

*After established tolerability to oral aripiprazole and completing starting regimen.

INDICATION

ARISTADA INITIO® (aripiprazole lauroxil) is a prescription medicine given as a **one-time injection** and is used in combination with oral aripiprazole to start ARISTADA® (aripiprazole lauroxil) 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 in adults.

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

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA

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).

Please see additional Important Safety Information throughout and full Prescribing Information for ARISTADA INITIO and ARISTADA, including Boxed Warning and Medication Guides for ARISTADA INITIO and ARISTADA.



Scan this QR code using your smartphone camera to watch a video about ARISTADA

Is a LONG-ACTING TREATMENT right for you?

The most common medicines for schizophrenia can be taken by mouth or by injection. Both of these options provide the treatment you need. The difference is how you take them.



LONG-ACTING INJECTABLES are given by your healthcare provider

are given by your healthcare provider and can offer different durations of treatment, depending on the medication chosen.



OPAL MEDICATIONS,

such as pills, are taken by mouth every day.

Ask your healthcare provider if ARISTADA® (aripiprazole lauroxil)

EVERY 2 MONTHS
(1064 mg) could be right for you.

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA (continued)

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.

Demonstrated in clinical studies to reduce SYMPTOMS OF SCHIZOPHRENIA in adult patients

Every person responds to schizophrenia medication differently. In clinical studies, ARISTADA® (aripiprazole lauroxil) was shown to reduce symptoms of schizophrenia.

Some common schizophrenia symptoms:

- Hallucinations
- Delusions
- Unusual thinking or disorganized speech
- Loss of motivation
- Disinterest or lack of enjoyment in daily activities
- Difficulty showing emotions
- Difficulty processing information to make decisions

These are not all of the symptoms of schizophrenia.

ARISTADA was shown to reduce symptoms of schizophrenia.



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1 dose can give you treatment for **2** MoNTHS

ARISTADA® is a long-acting injectable that can provide 2 months (1064 mg) of treatment. When receiving ARISTADA, you have one less medicine to remember to take every day.

After establishing tolerability to oral aripiprazole, you can start your treatment with ARISTADA (1064 mg) in one of two ways:

1) You will receive one injection of ARISTADA INITIO® (aripiprazole lauroxil) and one 30 mg dose of oral aripiprazole on the same day. Your first injection of ARISTADA will be given on that same day or within the following 10 days.

OR

2) On the first day, you will receive an injection of ARISTADA and then take oral aripiprazole daily for 21 days if ARISTADA INITIO is not right for you.

It's important not to miss a dose of ARISTADA.

If a dose is missed, contact your healthcare provider to discuss what to do next.



See if a **2-MoNTH** dosing option may be right for you

How often you are treated with ARISTADA® (aripiprazole lauroxil) depends on the dosage of medication that you and your healthcare provider decide is right for you.

Other dosing options include:

Every 2 months

Every 6 weeks

1064 mg

882 mg

441 mg
662 mg
882 mg

ARISTADA is slowly released into your body to last for weeks at a time with 1 injection.

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IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA (continued)

ARISTADA INITIO and/or ARISTADA may cause serious side effects including:

- 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
- sweating
- stiff muscles
- changes in pulse, heart
- confusion
- 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.

WHAT TO KNOW

before starting your treatment

- Before starting treatment with ARISTADA INITIO®
 (aripiprazole lauroxil) or ARISTADA® (aripiprazole lauroxil), tell your healthcare provider if you have not taken Abilify®, Abilify Maintena®, or any aripiprazole product before
- This is because people who are allergic to aripiprazole or any of the ingredients in ARISTADA should not receive ARISTADA or ARISTADA INITIO
- If you've never taken aripiprazole before, your healthcare provider may have you take oral aripiprazole for a short time to see if you can tolerate it before you start treatment

It's also important to tell your healthcare provider about all your medical conditions, including if you:

- Have or had heart problems or stroke
- Have diabetes or high blood sugar or a family history of diabetes or high blood sugar. Your healthcare provider should check on your blood sugar before you receive ARISTADA INITIO and/or 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 INITIO and/or ARISTADA will harm your unborn baby. If you become pregnant while on treatment, 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 womensmentalhealth.org/ research/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

Please see additional Important Safety Information throughout and full Prescribing Information for <u>ARISTADA INITIO</u> and <u>ARISTADA</u>, including Boxed Warning and Medication Guides for ARISTADA INITIO and ARISTADA.

Safety has been evaluated IN 1,180 PATIENTS*

ARISTADA may cause side effects

The most common side effect of ARISTADA® (aripiprazole lauroxil) is restlessness, also known as akathisia.

Other side effects are possible, some of them serious. Please see additional Important Safety Information throughout this brochure. You can also review the Medication Guides for ARISTADA and ARISTADA INITIO® for more information.

Remember to talk to your healthcare provider about any questions or concerns you have about starting treatment with ARISTADA.



To find a healthcare professional in your area who can administer ARISTADA INITIO and ARISTADA,

visit www.aristada.com/find-provider



*In clinical studies, 1,180 patients treated with ARISTADA were studied.

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA (continued)

ARISTADA INITIO and/or ARISTADA may cause serious side effects including:

- · Problems with your metabolism such as:
 - 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.



Please see additional Important Safety Information throughout and full Prescribing Information for <u>ARISTADA INITIO</u> and <u>ARISTADA</u>, including Boxed Warning and Medication Guides for <u>ARISTADA INITIO</u> and <u>ARISTADA</u>.

GETTING STARTED can happen in just one day

After discussing with your healthcare provider and establishing tolerability to oral aripiprazole, there are 3 steps to beginning your treatment:

- Your healthcare provider will give you a one-time injection of ARISTADA INITIO® (aripiprazole lauroxil) and a single 30 mg dose of oral aripiprazole.
 - Alternatively, your HCP could have you take oral aripiprazole for 21 days when you receive your first injection of ARISTADA® (aripiprazole lauroxil).
- You'll receive your first dose of ARISTADA either on the same day as ARISTADA INITIO or up to 10 days later.
- After receiving these initial doses, your following injections of ARISTADA (1064 mg) will be every 2 months unless you and your healthcare provider have decided on a different dosing option.

How ARISTADA is given:

- Both ARISTADA INITIO and ARISTADA are given by injection by a healthcare provider into the muscle (intramuscular)
- Depending on the dose, ARISTADA can be given in the upper arm (441 mg only) or buttock (all doses).
 ARISTADA INITIO can be given in either the upper arm or buttock
- Follow your ARISTADA treatment schedule exactly as your healthcare provider tells you to
- There are multiple dosing options for ARISTADA. Talk to your healthcare provider to see what is right for you

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA (continued)

ARISTADA INITIO and/or ARISTADA may cause serious side effects including:

- 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
- Increased fat levels (cholesterol and triglycerides) in your blood
- Weight gain. You and your healthcare provider should check your weight regularly.

Remember you can always ASK FOR SUPPORT



IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA (continued)

ARISTADA INITIO and/or ARISTADA may cause serious side effects including:

- 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.

ARISTADA Care Support is HERE TO HELP YOU



- If you have commercial insurance, you may be able to lower your out-of-pocket cost of treatment with ARISTADA® (aripiprazole lauroxil) through the ARISTADA Co-pay Savings Program*
- Patient Assistance Program for those who are eligible*
- *Eligibility requirements and terms and restrictions apply
- Help finding a healthcare provider who can administer ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA through the ARISTADA Provider Network

To speak to an ARISTADA Care Support representative, call 1-866-ARISTADA (1-866-274-7823), Monday through Friday, 9 AM to 8 PM ET.

Visit <u>aristada.com/resources</u> for more helpful links and information about living with schizophrenia.

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA (continued)

ARISTADA INITIO and/or ARISTADA may cause serious side effects including:

- 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.
 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.
- Difficulty swallowing

Please see additional Important Safety Information throughout and full Prescribing Information for ARISTADA INITIO and ARISTADA, including Boxed Warning and Medication Guides for ARISTADA INITIO and ARISTADA.



Here are some groups that can help you through your treatment journey:

National Alliance on Mental Illness
Visit www.nami.org or call
1-800-950-6264

Mental Health America
Visit www.mhanational.org or call
1-800-969-6642

Schizophrenia & Psychosis Action Alliance
Visit www.sczaction.org or call
1-800-493-2094

Alkermes, Inc. is not affiliated with and does not endorse the organizations named above. Resources named are provided for informational purposes only.



IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA

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 in adults.

It is not known if ARISTADA INITIO and/or ARISTADA are 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 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.

Please see additional Important Safety Information throughout and full Prescribing Information for <u>ARISTADA INITIO</u> and <u>ARISTADA</u>, including Boxed Warning and Medication Guides for ARISTADA INITIO and ARISTADA.

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA (continued)

- 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
 changes in pulse, heart rate, and blood pressure
 - sweating
- 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:
- 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
- Increased fat levels (cholesterol and triglycerides) in your blood
- Weight gain. You and your healthcare provider should check your weight regularly.

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA (continued)

- 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.
 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.
- · 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)

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA (continued)

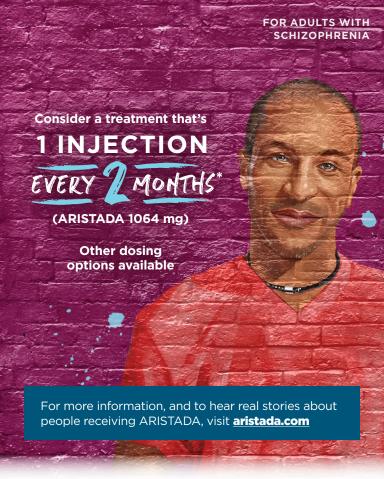
- · have or had a low white blood cell count
- have problems that may affect you receiving an injection in your buttocks or your arm
- are pregnant or plan to become pregnant. It is not known if ARISTADA INITIO and/or ARISTADA will harm your unborn baby. If you become pregnant while taking ARISTADA INITIO 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-researchprograms/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 additional Important Safety Information throughout and full Prescribing Information for ARISTADA INITIO and ARISTADA, including Boxed Warning and Medication Guides for ARISTADA INITIO and ARISTADA.



*After established tolerability to oral aripiprazole and completing starting regimen.

INDICATION

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

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IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA

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