

**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

For adults with schizophrenia

Interested in receiving treatment every 2 months?

*ASK YOUR DOCTOR
ABOUT ARISTADA (1064 mg)*

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 accompanying full Prescribing Information for [ARISTADA INITIO](#) and [ARISTADA](#), including Boxed Warning, and Medication Guides for [ARISTADA INITIO](#) and [ARISTADA](#).



WHY ARISTADA?

It's a schizophrenia treatment that provides the option of dosing every 2 months.



It has been shown to improve symptoms of schizophrenia



It's a long-acting treatment that's given by injection by a healthcare provider



Medicine is slowly released in your body over time



Provides the option of 6 doses a year



*It's one less medicine to take every day**

*After completing starting doses as directed by a healthcare provider.

- It's important you don't miss a dose of ARISTADA® (aripiprazole lauroxil). If you miss a dose for some reason, contact your doctor right away to discuss what you should do next

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for [ARISTADA INITIO](#) and [ARISTADA](#), including Boxed Warning, and Medication Guides for [ARISTADA INITIO](#) and [ARISTADA](#).

Talk to your doctor about starting treatment with ARISTADA.

**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



TREATMENT WITH ARISTADA

BEFORE STARTING TREATMENT

Before you start treatment with ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil), tell your healthcare provider if you have not taken Abilify®, Abilify Maintena®, or any aripiprazole product before. People who are allergic to aripiprazole or any of the ingredients in ARISTADA should not receive ARISTADA or ARISTADA INITIO.

See additional important information to discuss with your healthcare provider before receiving ARISTADA INITIO and/or ARISTADA on pages 14 to 15.

STARTING ARISTADA TREATMENT WITH ARISTADA INITIO

ON DAY 1, YOU WILL RECEIVE:

- A single 30 mg dose of oral aripiprazole
- A one-time injection of ARISTADA INITIO*
- Your first injection of ARISTADA, which can be given on the same day or up to 10 days later

*There are 2 ways to start treatment with ARISTADA. You may start your first ARISTADA injection with 21 days in a row of oral aripiprazole if your doctor determines ARISTADA INITIO is not right for you.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for [ARISTADA INITIO](#) and [ARISTADA](#), including Boxed Warning, and Medication Guides for [ARISTADA INITIO](#) and [ARISTADA](#).

*Talk to your doctor
about what dose may
be right for you.*



ARISTADA TREATMENT OPTIONS

ONCE EVERY 2 MONTHS
1064 mg dose

ONCE EVERY 6 WEEKS
882 mg dose

ONCE EVERY MONTH
441 mg, 662 mg, or 882 mg dose

HOW ARISTADA IS GIVEN

- Both ARISTADA INITIO and ARISTADA are given by injection into a muscle by a healthcare provider
- Depending on the dose, ARISTADA can be given in either the upper arm (441 mg dose 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

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA

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. (continued)**

**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

WHAT YOU SHOULD KNOW



You can learn more at
[aristada.com](https://www.aristada.com)

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for [ARISTADA INITIO](#) and [ARISTADA](#), including Boxed Warning, and Medication Guides for [ARISTADA INITIO](#) and [ARISTADA](#).

ARISTADA MAY HELP

- In a clinical study, ARISTADA® (aripiprazole lauroxil) showed an improvement in symptoms of schizophrenia
- Improving schizophrenia symptoms may help you reach your treatment goals

UNDERSTANDING SIDE EFFECTS

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

Other side effects are possible, some of them serious. Please see additional Important Safety Information throughout this brochure and on pages 12 to 15. You can also review the Medication Guides for ARISTADA INITIO and ARISTADA for more information.

Tell your doctor about any changes or side effects you have while taking ARISTADA INITIO or ARISTADA.

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA

ARISTADA INITIO and/or ARISTADA may cause serious side effects including: *(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
 - sweating
 - stiff muscles
 - changes in pulse, heart rate, and blood pressure
 - confusion

**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

WE ALL NEED SUPPORT

You don't have to do it alone

Reach out to these places for more support.

The Schizophrenia and Related Disorders Alliance of America (SARDAA)

www.sardaa.org
1-800-493-2094

Mental Health America (MHA)

www.mentalhealthamerica.net
1-800-969-6642

The National Alliance on Mental Illness (NAMI)

www.nami.org
1-800-950-6264



Please see additional Important Safety Information throughout and accompanying full Prescribing Information for [ARISTADA INITIO](#) and [ARISTADA](#), including Boxed Warning, and Medication Guides for [ARISTADA INITIO](#) and [ARISTADA](#).

ARISTADA CARE SUPPORT

Support services are available every step of the way

ARISTADA Care Support is a support program that provides access to services, such as:



Appointment confirmations and reminders



Help finding healthcare providers near you who can administer ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil)



Co-pay and patient assistance programs for ARISTADA for those who are eligible

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

**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

QUESTIONS TO ASK YOUR DOCTOR

1 *Could ARISTADA® (aripiprazole lauroxil) be a good treatment option for me?*

2 *What are the possible side effects of ARISTADA?*

3 *What if I miss an appointment to get my ARISTADA injection?*

4 *Which ARISTADA dose could be right for me?*



Please see additional Important Safety Information throughout and accompanying full Prescribing Information for [ARISTADA INITIO](#) and [ARISTADA](#), including Boxed Warning, and Medication Guides for [ARISTADA INITIO](#) and [ARISTADA](#).

NOTES

This brochure is not intended to substitute for professional medical advice or judgment.

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA

ARISTADA INITIO and/or ARISTADA may cause serious side effects including: *(continued)*

- **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.

**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

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 accompanying full Prescribing Information for [ARISTADA INITIO](#) and [ARISTADA](#), 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
 - sweating
 - 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:**
 - **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.

(continued)

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

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

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA (continued)

Before receiving ARISTADA INITIO and ARISTADA tell your healthcare provider about all of your medical conditions, including if you: (continued)

- 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.

**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



ASK YOUR DOCTOR ABOUT THE ARISTADA 2-MONTH DOSE (1064 mg)

*Images are not
actual patients*

Visit aristada.com

Find out if ARISTADA may be right for you

- It has been shown to improve symptoms of schizophrenia in adults
- It provides the option of 6 doses a year
- You should not miss a dose of ARISTADA® (aripiprazole lauroxil). If you miss a dose for some reason, call your healthcare provider right away to discuss what you should do next

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 accompanying full Prescribing Information for [ARISTADA INITIO](#) and [ARISTADA](#), including Boxed Warning, and Medication Guides for [ARISTADA INITIO](#) and [ARISTADA](#).

**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

Alkermes®

ALKERMES® is a registered trademark of Alkermes, Inc. ARISTADA® and logo, and ARISTADA INITIO®, are registered trademarks of Alkermes Pharma Ireland Limited, used by Alkermes, Inc., under license. ABILIFY® is a trademark of Otsuka Pharmaceutical Company and ABILIFY MAINTENA® is a trademark of Otsuka Pharmaceutical Co., Ltd. ©2019 Alkermes, Inc. All rights reserved. ARI-003759-v1