ARISTADA INITIO® AND ARISTADA®

DOSING & PHARMACY ORDERING INFORMATION

With one injection of ARISTADA INITIO and a single dose of oral aripiprazole plus ARISTADA 1064 mg, you can fully dose on day 1 for 2 months of treatment [1,2]

INDICATION

ARISTADA INITIO® (aripiprazole lauroxil), in combination with oral aripiprazole, is indicated for the initiation of ARISTADA® (aripiprazole lauroxil) when used for the treatment of schizophrenia in adults.

ARISTADA is an atypical antipsychotic indicated for the treatment of schizophrenia in adults.

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ARISTADA INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.

Contraindication: Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

Please see additional Important Safety Information and accompanying full Prescribing Information, including Boxed Warning, 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

ARISTADA INITIO DOSING AND ADMINISTRATION

ARISTADA INITIO reduces oral aripiprazole supplementation to 1 day[1]

ARISTADA INITIO® (aripiprazole lauroxil) is only to be used as a single dose to initiate ARISTADA® (aripiprazole lauroxil) treatment or as a single dose to re-initiate ARISTADA treatment following a missed dose of ARISTADA. ARISTADA INITIO is not for repeated dosing.[1]

DAY 1

STEP 1

After establishing tolerability with oral aripiprazole, give patients a ***one-time*** ARISTADA INITIO injection and a single 30 mg dose of oral aripiprazole[1]

1 ARISTADA INITIO DOSE AND A SINGLE 30 MG DOSE OF ORAL ARIPIPRAZOLE

DAY 1

STEP 2

Select ***one*** ARISTADA dose and give on the same day or up to 10 days later if desired[2]

441 mg | 662 mg | 882 mg | 1064 mg

FIRST ARISTADA DOSE

Important dosing considerations

- ARISTADA INITIO and ARISTADA are not interchangeable because of differing pharmacokinetic profiles[1]
- ARISTADA INITIO and ARISTADA are only to be administered as an intramuscular injection by a healthcare professional[1,2]
- For patients who have never taken aripiprazole, establish tolerability with oral aripiprazole prior to initiating ARISTADA or ARISTADA INITIO[1,2]
- ARISTADA INITIO can be administered in the deltoid or gluteal muscle. Administer ARISTADA intramuscular injection in the gluteal muscle (all doses) or deltoid muscle (441 mg dose only). Avoid injecting both ARISTADA and ARISTADA INITIO concomitantly into the same deltoid or gluteal muscle[1]
- ARISTADA INITIO is only available at a single strength as a single-dose pre-filled syringe, so dosage adjustments are not possible. Therefore, avoid use in patients who are known CYP2D6 poor metabolizers or taking strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or strong CYP3A4 inducers, antihypertensive drugs or benzodiazepines[1]
- There are two ways to start treatment with ARISTADA. If not starting ARISTADA with ARISTADA INITIO, administer 21 consecutive days of oral aripiprazole with the first ARISTADA injection[2]

Please see additional Important Safety Information and accompanying full Prescribing Information, including Boxed Warning, 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

ARISTADA DOSING

ARISTADA® (aripiprazole lauroxil) can be started at any dose[2]

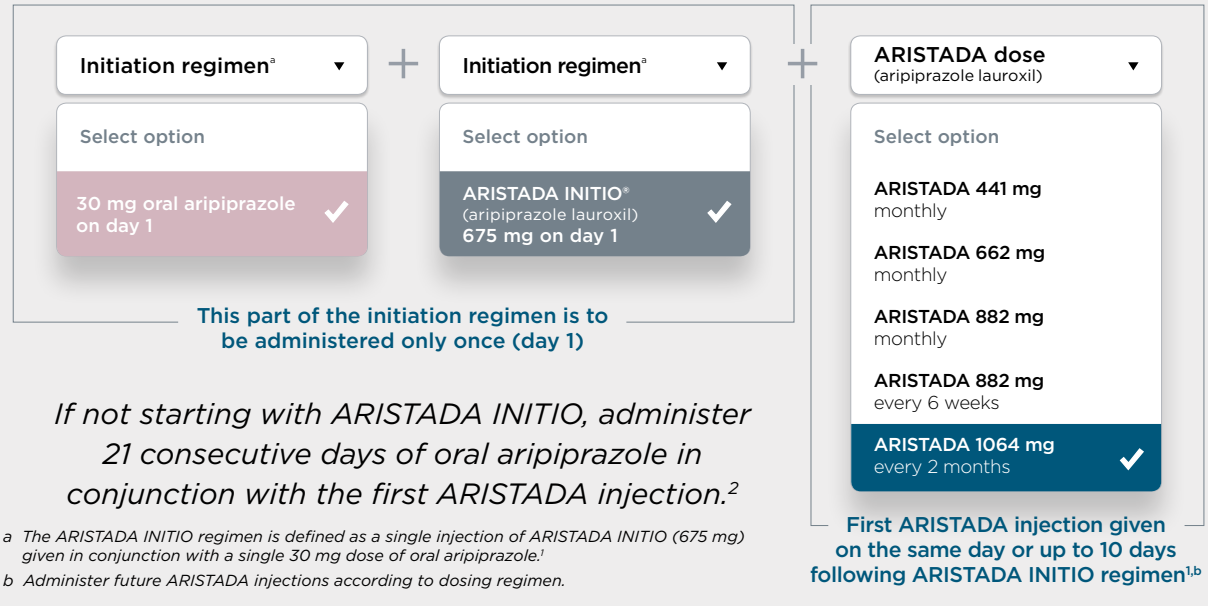
DOSING INTERVALS FOR ARISTADA[2]

- ARISTADA **1064 MG** | EVERY 2 MONTHS
- ARISTADA **882 MG** | EVERY 6 WEEKS
- ARISTADA **882 MG** | MONTHLY
- ARISTADA **662 MG** | MONTHLY
- ARISTADA **441 MG** | MONTHLY

The **2-month dose** (1064 mg) provides the longest dosing interval of ARISTADA.

SELECT ALL 3 COMPONENTS WHEN STARTING ARISTADA

Example illustrates prescribing ARISTADA INITIO and ARISTADA 2-month dose



If not starting with ARISTADA INITIO, administer 21 consecutive days of oral aripiprazole in conjunction with the first ARISTADA injection.[2]

a The ARISTADA INITIO regimen is defined as a single injection of ARISTADA INITIO (675 mg) given in conjunction with a single 30 mg dose of oral aripiprazole.[1]

b Administer future ARISTADA injections according to dosing regimen.

This guide does not contain all of the information needed to administer ARISTADA INITIO or ARISTADA. Please refer to the full Prescribing Information and package labeling for additional instruction on dosing and administration, and Instructions for Use.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Cerebrovascular Adverse Reactions, Including Stroke: Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities, have been reported in placebo-controlled trials of elderly patients with dementia-related psychosis treated with risperidone, aripiprazole, and olanzapine. ARISTADA INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.

Please see additional Important Safety Information and accompanying full Prescribing Information, including Boxed Warning, 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

HOW SUPPLIED

ARISTADA INITIO® (aripiprazole lauroxil)

	NDC	Dose	Quantity	WAC
	65757-0500-03	The 675-mg strength kit (gray label) contains 3 safety needles: • 1-inch (25 mm) 21 gauge • 1½-inch (38 mm) 20 gauge • 2-inch (50 mm) 20 gauge needle	One kit	$1,981.73 per unit

ARISTADA® (aripiprazole lauroxil)

	NDC	Dose	Quantity	WAC
	65757-0401-03	The 441-mg strength kit (light blue label) contains 3 safety needles: • 1-inch (25 mm) 21 gauge • 1½-inch (38 mm) 20 gauge • 2-inch (50 mm) 20 gauge	One kit	$1,294.73 per unit
	65757-0402-03	The 662-mg strength kit (green label) contains 2 safety needles: • 1½-inch (38 mm) 20 gauge • 2-inch (50 mm) 20 gauge	One kit	$1,943.56 per unit
	65757-0403-03	The 882-mg strength kit (burgundy label) contains 2 safety needles: • 1½-inch (38 mm) 20 gauge • 2-inch (50 mm) 20 gauge	One kit	$2,589.46 per unit
	65757-0404-03	The 1064-mg strength kit (dark blue label) contains 2 safety needles • 1½-inch (38 mm) 20 gauge • 2-inch (50 mm) 20 gauge	One kit	$3,123.79 per unit

IMPORTANT SAFETY INFORMATION (CONTINUED)

Potential for Dosing and Medication Errors: Medication errors, including substitution and dispensing errors, between ARISTADA INITIO and ARISTADA could occur. ARISTADA INITIO is intended for single administration in contrast to ARISTADA which is administered monthly, every 6 weeks, or every 8 weeks. Do not substitute ARISTADA INITIO for ARISTADA because of differing pharmacokinetic profiles.

Please see additional Important Safety Information and accompanying full Prescribing Information, including Boxed Warning, 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

STORAGE INFORMATION FOR ARISTADA INITIO AND ARISTADA

Store each product properly per instructions on carton(s).

ARISTADA INITIO Storage[1]

- ARISTADA INITIO® (aripiprazole lauroxil) should be stored at room temperature 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C and 30°C (between 59°F and 86°F). **Do not freeze**
- ARISTADA INITIO cartons should lay flat when stored and should not be shelved vertically. The carton is shaped to assist with proper storage. Proper storage of ARISTADA INITIO should help prevent excessive sedimentation near the needle hub

ARISTADA Storage[2]

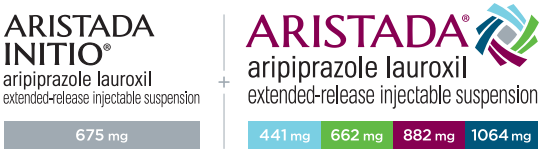
- ARISTADA® (aripiprazole lauroxil) should be stored at room temperature 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C and 30°C (between 59°F and 86°F)

IMPORTANT SAFETY INFORMATION (CONTINUED)

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex may occur with administration of antipsychotic drugs, including ARISTADA INITIO and ARISTADA. Clinical manifestations of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

Tardive Dyskinesia (TD): The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing antipsychotics should be consistent with the need to minimize TD. Discontinue ARISTADA if clinically appropriate. TD may remit, partially or completely, if antipsychotic treatment is withdrawn.

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



ORDERING INFORMATION FOR ARISTADA INITIO

ARISTADA INITIO® (aripiprazole lauroxil) can be ordered from the following sources:

Wholesaler/ Distributor	Phone	Website	ARISTADA INITIO 675 mg Item #
AmerisourceBergen	1-610-727-7000	www.amerisourcebergen.com	10188766
McKesson	1-800-793-9875	www.mckesson.com	3919800
Cardinal	1-800-926-3161	www.cardinal.com	5464953
HD Smith	1-866-232-1222	www.hdsmith.com	572-6302
Kinray	1-888-527-6806	www.kinray.com	734984
Smith Drug/Burlington	1-800-542-1216	www.smithdrug.com	853168
Rochester Drug	1-800-333-0538	www.rdcdrug.com	10772333
Value Drug	1-800-252-3786	www.valuedrugco.com	194844
Morris & Dickson	1-800-388-3833	www.morrisdickson.com	380865
Dakota Drug	1-866-210-5887	www.dakdrug.com	390831
N.C. Mutual Drug	1-800-800-8551	www.mutualdrug.com	318949
ANDA Inc.	1-800-331-2632	www.andanet.com	804692
Louisiana Wholesale	1-800-960-3784	www.lwdrx.com	210237
R&S Northeast	1-800-262-7770	www.rsnortheast.com	050003*
Prescription Supply	1- 800-777-0761	www.prescriptionsupply.com	962910
QK Healthcare	1-855-795-6979	www.qkrx.com	74360

* Not stocked but will order on demand.

To order ARISTADA INITIO and ARISTADA, contact your Wholesaler/Distributor.

For product information, call 1-866-ARISTADA (1-866-274-7823) or visit www.ARISTADAhcp.com.

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

ORDERING INFORMATION FOR ARISTADA

ARISTADA® (aripiprazole lauroxil) can be ordered from the following sources:

Wholesaler/ Distributor	Phone	Website	ARISTADA 441 mg Item #	ARISTADA 662 mg Item #	ARISTADA 882 mg Item #	ARISTADA 1064 mg Item #
AmerisourceBergen	1-610-727-7000	www.amerisourcebergen.com	10158930	10158907	10158906	10178590
McKesson	1-800-793-9875	www.mckesson.com	3489051	3489069	3489077	3670726
Cardinal	1-800-926-3161	www.cardinal.com	5161427	5161492	5161567	5368352
HD Smith	1-866-232-1222	www.hdsmith.com	551-7206	551-7214	551-7222	566-8843
Kinray	1-888-527-6806	www.kinray.com	411169	411177	411195	5368352
Smith Drug/Burlington	1-800-542-1216	www.smithdrug.com	741918	741900	741926	809780
Rochester Drug	1-800-333-0538	www.rdcdrug.com	10698942	10698959	10698967	10737922
Value Drug	1-800-252-3786	www.valuedrugco.com	146044	146048	146046	175878
Morris & Dickson	1-800-388-3833	www.morrisdickson.com	398776	398834	399311	981852
Dakota Drug	1-866-210-5887	www.dakdrug.com	262188	262204	262212	312314
N.C. Mutual Drug	1-800-800-8551	www.mutualdrug.com	195024	195032	195040	270538
ANDA Inc.	1-800-331-2632	www.andanet.com	804348	804349	804350	804531
Louisiana Wholesale	1-800-960-3784	www.lwdrx.com	166165	166173	166181	189589
R&S Northeast	1-800-262-7770	www.rsnortheast.com	040103*	040203*	0403030*	040403*
Prescription Supply	1-800-777-0761	www.prescriptionsupply.com	962886	961599	958892	962902
QK Healthcare	1-855-795-6979	www.qkrx.com	74354	74358	74359	74361

* Not stocked but will order on demand.

To order ARISTADA INITIO and ARISTADA, contact your Wholesaler/Distributor.

For product information, call 1-866-ARISTADA (1-866-274-7823) or visit www.ARISTADAhcp.com.

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

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, in combination with oral aripiprazole, is indicated for the initiation of ARISTADA when used for the treatment of schizophrenia in adults.

ARISTADA is indicated for the treatment of schizophrenia in adults.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ARISTADA INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.

Contraindication: Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

Cerebrovascular Adverse Reactions, Including Stroke: Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities, have been reported in placebo-controlled trials of elderly patients with dementia-related psychosis treated with risperidone, aripiprazole, and olanzapine. ARISTADA INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.

Potential for Dosing and Medication Errors: Medication errors, including substitution and dispensing errors, between ARISTADA INITIO and ARISTADA could occur. ARISTADA INITIO is intended for single administration in contrast to ARISTADA which is administered monthly, every 6 weeks, or every 8 weeks. Do not substitute ARISTADA INITIO for ARISTADA because of differing pharmacokinetic profiles.

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex may occur with administration of antipsychotic drugs, including ARISTADA INITIO and ARISTADA. Clinical manifestations of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

Tardive Dyskinesia (TD): The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses.

Prescribing antipsychotics should be consistent with the need to minimize TD. Discontinue ARISTADA if clinically appropriate. TD may remit, partially or completely, if antipsychotic treatment is withdrawn.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that include:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics. There have been reports of hyperglycemia in patients treated with oral aripiprazole. Patients with diabetes should be regularly monitored for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia, including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients require continuation of antidiabetic treatment despite discontinuation of the suspect drug.
- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.
- **Weight Gain**: Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Pathological Gambling and Other Compulsive Behaviors: Compulsive or uncontrollable urges to gamble have been reported with use of aripiprazole. Other compulsive urges less frequently reported include sexual urges, shopping, binge eating and other impulsive or compulsive behaviors which may result in harm for the patient and others if not recognized. Closely monitor patients and consider dose reduction or stopping aripiprazole if a patient develops such urges.

Orthostatic Hypotension: Aripiprazole may cause orthostatic hypotension which can be associated with dizziness, lightheadedness, and tachycardia. Monitor heart rate and blood pressure, and warn patients with known cardiovascular or cerebrovascular disease and risk of dehydration and syncope.

Falls: Antipsychotics including ARISTADA INITIO and ARISTADA may cause somnolence, postural hypotension or motor and sensory instability which may lead to falls and subsequent injury. Upon initiating treatment and recurrently, complete fall risk assessments as appropriate.

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia, neutropenia and agranulocytosis have been reported with antipsychotics. Monitor complete blood count in patients with pre-existing low white blood cell count (WBC)/absolute neutrophil count or history of drug-induced leukopenia/neutropenia. Discontinue ARISTADA INITIO and/or ARISTADA at the first sign of a clinically significant decline in WBC and in severely neutropenic patients.

Seizures: Use with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Potential for Cognitive and Motor Impairment: ARISTADA INITIO and ARISTADA may impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are certain therapy with ARISTADA INITIO and/or ARISTADA does not affect them adversely.

Body Temperature Regulation: Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Advise patients regarding appropriate care in avoiding overheating and dehydration. Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration.

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use; use caution in patients at risk for aspiration pneumonia.

Concomitant Medication: ARISTADA INITIO is only available at a single strength as a single-dose pre-filled syringe, so dosage adjustments are not possible. Avoid use in patients who are known CYP2D6 poor metabolizers or taking strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or strong CYP3A4 inducers, antihypertensive drugs or benzodiazepines.

Depending on the ARISTADA dose, adjustments may be recommended if patients are 1) known as CYP2D6 poor metabolizers and/or 2) taking strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or strong CYP3A4 inducers for greater than 2 weeks. Avoid use of ARISTADA 662 mg, 882 mg, or 1064 mg for patients taking both strong CYP3A4 inhibitors and strong CYP2D6 inhibitors. (See Table 4 in the ARISTADA full Prescribing Information.)

Commonly Observed Adverse Reactions: In pharmacokinetic studies the safety profile of ARISTADA INITIO was generally consistent with that observed for ARISTADA. The most common adverse reaction (≥5% incidence and at least twice the rate of placebo reported by patients treated with ARISTADA 441 mg and 882 mg monthly) was akathisia.

Injection-Site Reactions: In pharmacokinetic studies evaluating ARISTADA INITIO, the incidences of injection-site reactions with ARISTADA INITIO were similar to the incidence observed with ARISTADA. Injection-site reactions were reported by 4%, 5%, and 2% of patients treated with 441 mg ARISTADA (monthly), 882 mg ARISTADA (monthly), and placebo, respectively. Most of these were injection-site pain and associated with the first injection and decreased with each subsequent injection. Other injection-site reactions (induration, swelling, and redness) occurred at less than 1%.

Dystonia: Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first days of treatment and at low doses.

Pregnancy/Nursing: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Advise patients to notify their healthcare provider of a known or suspected pregnancy. Inform patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ARISTADA INITIO and/or ARISTADA during pregnancy. Aripiprazole is present in human breast milk. The benefits of breastfeeding should be considered along with the mother's clinical need for ARISTADA INITIO and/or ARISTADA and any potential adverse effects on the infant from ARISTADA INITIO and/or ARISTADA or from the underlying maternal condition.

Please see full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

References: 1. ARISTADA INITIO® (aripiprazole lauroxil) [package insert] Waltham, MA: Alkermes Inc.; 2018. 2. ARISTADA® (aripiprazole lauroxil) [package insert] Waltham, MA: Alkermes Inc.; 2018.

Alkermes®

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