



### Aripiprazole

- Oral tablet: 2 mg, 5mg, 10 mg, 15 mg, 20 mg, 30 mg
- Orally disintegrating tablet: 10 mg,
  15 mg
- Oral solution: 1 mg/mL

### Abilify<sup>®</sup>

Tablet: 2 mg, 5mg, 10 mg, 15 mg, 20 mg, 30 mg

#### Abilify Asimtufii<sup>®</sup> (aripiprazole)

 Extended-release injectable suspension: 720 mg/2.4 mL, 960 mg/3.2 mL

#### Abilify MyCite®

Oral tablet with a digestible sensor:
 2 mg, 5mg, 10 mg, 15 mg, 20 mg, 30 mg

#### Abilify Maintena<sup>®</sup>

 Extended-release injectable suspension: 300 mg, 400 mg

#### • Aristada® (aripiprazole lauroxil)

Extended-release injectable
 suspension: 441 mg, 662 mg, 882
 mg, 1064 mg

### Aristada Initio<sup>®</sup> (aripiprazole lauroxil)

 Extended-release injectable suspension: 675 mg If you or someone you know is in crisis, please call/text 988 to speak with a trained crisis counselor 24/7 and/or call 911 for emergency services. A help line and other resources are also available through the National Alliance on Mental Illness at nami.org.



## What is aripiprazole and what does it treat?

Aripiprazole is a medication that works in the brain to treat schizophrenia. It is also known as a second-generation antipsychotic (SGA) or atypical antipsychotic. Aripiprazole rebalances dopamine and serotonin to improve thinking, mood, and behavior.

Symptoms of schizophrenia include:

- Hallucinations hearing or seeing things that feel real but others do not hear/see
- Delusions beliefs that are not true (e.g., other people are reading your thoughts)
- Disorganized thinking trouble organizing your thoughts and making sense
- Little desire to be around other people
- Trouble speaking clearly
- Lack of motivation

Aripiprazole may help some or all of these symptoms.

Aripiprazole is also FDA approved for the following indications:

- Acute treatment of manic or mixed episodes of Bipolar I Disorder
- Maintenance treatment of Bipolar Disorder
- Adjunctive treatment of Major Depressive Disorder (this means aripiprazole is used in addition to an antidepressant to help treat depression)
- Irritability associated with Autism Spectrum Disorder
- Tourette's Syndrome

This medication sheet will focus primarily on schizophrenia. You can find more information about bipolar disorder, depression, and autism spectrum disorders <a href="here">here</a>.

Aripiprazole may also be helpful when prescribed "off-label" for borderline personality disorder or drug-induced hyperprolactinemia (elevated prolactin levels caused by other antipsychotics). "Off-label" means that it hasn't been approved by the Food and Drug Administration for this condition. Your mental health provider should justify his or her thinking in recommending an "off-label" treatment. They should be clear about the limits of the research around that medication and if there are any other options.

All FDA warnings are at the end of this fact sheet. Please consult them before taking this medication.



## What is the most important information I should know about aripiprazole?

Schizophrenia, bipolar disorder, and many other mental health conditions requires long-term treatment.

Do not stop taking aripiprazole, even when you feel better.

With input from you, your health care provider will help guide you on how long you will need to take the medicine.

For aripiprazole to work properly, it should be taken every day as ordered by your health care provider.

Missing doses of aripiprazole may increase your risk for a relapse (or return/worsening) of your symptoms.

Do not stop taking aripiprazole or change your dose without talking with your health care provider first.

## Are there specific concerns about aripiprazole and pregnancy?

If you are planning on becoming pregnant, talk to your health care provider about how to best manage your medications. People living with a mental health condition who wish to become pregnant face important decisions. This is a complex decision since untreated schizophrenia, bipolar disorder, and depression can have a risk to the fetus and mother as well.

It is important to discuss the risks and benefits of treatment with your doctor and caregivers. Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and/or withdrawal symptoms in newborns following delivery that may need to be monitored. These may resolve within hours/days without treatment or require hospitalization for monitoring/treatment.

The health benefits of breastfeeding while taking aripiprazole should be considered along with the mother's clinical need for aripiprazole and possible effects on the breastfeed infant from aripiprazole. In general, infants exposed to SGAs via breast milk should be monitored weekly for the first month of exposure for symptoms, such as appetite changes, insomnia, irritability, or lethargy.

# What should I discuss with my health care provider before taking aripiprazole?

- Symptoms of your condition that bother you the most
- If you have thoughts of suicide or harming yourself
- Medications you have taken in the past for your condition and whether they were effective or caused any adverse effects
- If you ever had muscle stiffness, shaking, tardive dyskinesia, neuroleptic malignant syndrome, or weight gain caused by a medication
- If you experience side effects from your medications as some side effects may pass with time, but others may require changes in the medication
- Any psychiatric or medical problems you have including heart rhythm problems, long QT syndrome, heart attacks, diabetes, high cholesterol, or seizures
- If you have a family history of diabetes or heart disease
- All other medications you are currently taking (including over the counter products, herbal and nutritional supplements) and any medication allergies you have
- Other non-medication treatment you are receiving, such as talk therapy or substance abuse treatment. Your provider can explain how these different treatments work with the medication.
- If you are pregnant, plan to become pregnant, or are breastfeeding
- If you smoke, drink alcohol, or use illegal drugs

# How should I take aripiprazole?

Aripiprazole tablets and suspension are usually taken 1 time per day with or without food. Typically, patients begin at a low dose of medicine and the dose is increased slowly over several weeks. The oral dose of aripiprazole usually ranges from 2 mg to 30 mg taken once daily.

Use a calendar, pillbox, alarm clock, or cell phone alert to help you remember to take your medication. You may also ask a family member or a friend to remind you or check in with you to be sure you are taking your medication.



Once people try the oral form of aripiprazole, some may make the decision with their health care provider to switch to the injection form. There are multiple types of injection forms that include:

- Abilify Asimtufii<sup>®</sup> (aripiprazole) which is given every 2 months (56 days).
- Abilify Maintena® which is given every 1 month.
- Aristada<sup>®</sup> (aripiprazole lauroxil) which is given every 1 month, 6 weeks, or 2 months depending on the dose.

When you first switch to the injection form, your health care provider will provide you instructions on when to stop taking the oral medications as some injections need you to continue taking the oral medication for 2-3 weeks after the first injection. Only your health care provider can determine the correct form and dose for you.

## What happens if I miss a dose of aripiprazole?

If you miss a dose of oral aripiprazole, take it as soon as you remember, unless it is closer to the time of your next dose. Do not double your next dose or take more than what is prescribed. If you miss an injection, call your doctor or pharmacist right away.

## What should I avoid while taking aripiprazole?

Avoid drinking alcohol or using illegal drugs while you are taking aripiprazole. They may decrease the benefits (e.g., worsen your symptoms) and increase side effects (e.g., sedation) of the medication.

# What happens if I overdose with aripiprazole?

If an overdose occurs, call your doctor or 911. You may need urgent medical care. You may also contact the poison control center at 1-800-222-1222.

A specific treatment to reverse the effects of aripiprazole does not exist.

# What are the possible side effects of aripiprazole?

### **Common side effects**

Nausea, vomiting, constipation, headache, dizziness, restlessness, insomnia, fatigue, anxiety, weight gain, changes in cholesterol or blood sugar, application site rash (with MyCite® form), injection site pain (with injection forms)

#### Rare/serious side effects

Rare and serious side effects can occur with all medications and may be affected by people's individual risk factors. For aripiprazole these include: rash, dry mouth, muscle aches, seizure, agitation

Some people may develop muscle-related side effects while taking aripiprazole. The technical terms for these are "extrapyramidal symptoms" (EPS) and "tardive dyskinesia" (TD). Symptoms of EPS include restlessness, tremor, and stiffness. TD symptoms include slow or jerky movements that one cannot control, often starting in the mouth with tongue rolling or chewing movements.

All antipsychotics can cause sedation, dizziness, or orthostatic hypotension which is a drop in blood pressure when standing up from sitting or lying down. These side effects may lead to falls or other injuries. This risk is higher for people with conditions or other medications that could worsen these effects. If falls or any of these symptoms occur, contact your health care provider.

Antipsychotics can also affect temperature regulation especially if you are in an area that is very hot or are exercising very heavily. While taking aripiprazole, it is especially important to try to drink water to avoid dehydration.

Second generation antipsychotics (SGAs) increase the risk of weight gain, high blood sugar, and high cholesterol. This is also known as metabolic syndrome. Your health care provider may ask you for a blood sample to check your cholesterol, blood sugar, and hemoglobin A1c (a measure of blood sugar over time) while you take this medication.

- Information on healthy eating and adding exercise to decrease your chances of developing metabolic syndrome may be found at the following sites:
  - http://www.helpguide.org/articles/healthy-eating/healthy-eating.htm
  - o <a href="http://www.helpguide.org/home-pages/exercise-fitness.htm">http://www.helpguide.org/home-pages/exercise-fitness.htm</a>



Antipsychotics may increase the blood levels of a hormone called prolactin. Side effects of increased prolactin levels include females losing their period, production of breast milk and males losing their sex drive or possibly experiencing erectile problems.

Neuroleptic malignant syndrome is a rare, life-threatening adverse effect of antipsychotics which occurs in <1% of patients. Symptoms include confusion, fever, extreme muscle stiffness, and sweating. If any of these symptoms occur, contact your health care provider immediately.

The U.S. Food and Drug Administration (FDA) is warning that compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex have been reported with the use of aripiprazole (Abilify®, Abilify Maintena®, Aristada®, Aristada Initio®). These uncontrollable urges stopped when the medicine was discontinued, or the dose was reduced.

# Are there any risks for taking aripiprazole for long periods of time?

Tardive dyskinesia (TD) is a side effect that develops with prolonged use of antipsychotics. Medications such as aripiprazole have been shown to have a lower risk of TD compared to older antipsychotics, such as Haldol® (haloperidol). If you develop symptoms of TD, such as grimacing, sucking, and smacking of lips, or other movements that you cannot control, contact your health care provider immediately. All patients taking either first or second generation antipsychotics should have an Abnormal Involuntary Movement Scale (AIMS) completed regularly by their health care provider to monitor for TD.

Second generation antipsychotics (SGAs) increase the risk of diabetes, weight gain, high cholesterol, and high triglycerides. (See "Serious Side Effects" section for monitoring recommendations).

# What other medications may interact with aripiprazole?

The following medications may increase the levels and effects of aripiprazole:

- The antibiotic clarithromycin (Biaxin®)
- Antidepressants, such as fluoxetine (Prozac®), paroxetine (Paxil®), and nefazodone
- Antifungals, such as fluconazole (Diflucan®), ketoconazole (Nizoral®), and itraconazole (Sporanox®)
- The antiarrhythmic agent quinidine
- HIV medications, such as the protease inhibitors indinavir (Crixivan®), ritonavir (Norvir®), saquinavir (Fortovase®, Invirase®), and lopinavir/ritonavir (Kaletra®)

The following medications may decrease the levels and effects of aripiprazole: carbamazepine (Tegretol®) and rifampin (Rifadin®).

## How long does it take for aripiprazole to work?

It is very important to tell your doctor how you feel things are going during the first few weeks after you start taking aripiprazole. It will probably take several weeks to see big enough changes in your symptoms to decide if aripiprazole is the right medication for you.

Antipsychotic treatment is generally needed lifelong for persons with schizophrenia. Your doctor can best discuss the duration of treatment you need based on your symptoms and illness.

- Hallucinations, disorganized thinking, and delusions may improve in the first 1-2 weeks
- Sometimes these symptoms do not completely go away
- Motivation and desire to be around other people can take at least 1-2 weeks to improve
- Symptoms continue to get better the longer you take aripiprazole
- It may take 2-3 months before you get the full benefit of aripiprazole

# Summary of Black Box Warnings

### **Increased Mortality in Elderly Patients with Dementia Related Psychosis**

- When used for dementia related psychosis in elderly people, both first generation (typical) and second generation (atypical) antipsychotics are associated with an increased risk of mortality.
- Although there were multiple causes of death in studies, most deaths appeared to be due to cardiovascular causes (e.g., sudden cardiac death) or infection (e.g., pneumonia).



### Suicidal Thoughts or Actions in Children, Teens, and Young Adults

Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide.

- Patients treated with antidepressants may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking medications. This risk may persist until significant symptom improvement (or remission) occurs.
- Patients, their families, and caregivers should be alert to the emergence of anxiety, restlessness, irritability, aggressiveness and insomnia. If these symptoms emerge, they should be reported to the patient's prescriber or health care professional.
- All patients being treated with aripiprazole for depression should watch for and notify their health care provider for worsening symptoms, suicidality and unusual changes in behavior, especially during the first few months of treatment.

Important Disclosure: This information is being provided as a community outreach effort of the American Association of Psychiatric Pharmacists. This information is for educational and informational purposes only and is not medical advice. This information contains a summary of important points and is not an exhaustive review of information about the medication. Always seek the advice of a physician or other qualified medical professional with any questions you may have regarding medications or medical conditions. Never delay seeking professional medical advice or disregard medical professional advice as a result of any information provided herein. The American Association of Psychiatric Pharmacists disclaims any and all liability alleged as a result of the information provided herein.