MEDICATION GUIDE

Aripiprazole

(ar″ i pip′ ra zole)

Oral Solution

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

(For other side effects, also see "What are the possible side effects of aripiprazole oral solution?")

Serious side effects may happen when you take aripiprazole oral solution, including:

- **Increased risk of death in elderly patients with dementia-related psychosis:** Medicines like aripiprazole oral solution can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). Aripiprazole oral solution is not approved for the treatment of patients with dementia- related psychosis.
- **Risk of suicidal thoughts or actions:** Antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions:
  1. **Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.**
  2. **Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions.** These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.
  3. **How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**
     - Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
     - Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
     - Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability

- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

What else do I need to know about antidepressant medicines?

- **Never stop an antidepressant medicine without first talking to a healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.
- **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.
- **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.
- **Not all antidepressant medicines prescribed for children are FDA approved for use in children.** Talk to your child's healthcare provider for more information.

What is aripiprazole oral solution?

- **Aripiprazole Oral Solution is prescription medicine used to treat:**
  - Schizophrenia
  - manic or mixed episodes that happen with bipolar I disorder
  - major depressive disorder (MDD) when aripiprazole oral solution is used with antidepressant medicines
  - irritability associated with autistic disorder
  - Tourette's disorder

It is not known if aripiprazole oral solution is safe or effective in children:

- under 13 years of age with schizophrenia
- under 10 years of age with bipolar I disorder
- under 6 years of age with irritability associated with autistic disorder
- under 6 years of age with Tourette's disorder

Do not take aripiprazole oral solution if you are allergic to aripiprazole or any of the ingredients in aripiprazole oral solution. See the end of this Medication Guide for a complete list of ingredients in aripiprazole oral solution.

Before taking aripiprazole oral solution, tell your healthcare provider about all your medical conditions, including if you have or had:

- diabetes or high blood sugar in you or your family; your healthcare provider should check your blood sugar before you start aripiprazole oral solution and also during therapy.

- seizures (convulsions).
- low or high blood pressure.
- heart problems or stroke.
- pregnancy or plans to become pregnant. It is not known if aripiprazole oral solution will harm your unborn baby.
    - If you become pregnant while receiving aripiprazole oral solution, 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 go to http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/.
- breast-feeding or plans to breast-feed. Aripiprazole passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive aripiprazole oral solution.
- low white blood cell count.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Aripiprazole oral solution and other medicines may affect each other causing possible serious side effects. Aripiprazole oral solution may affect the way other medicines work, and other medicines may affect how Aripiprazole oral solution works.
Your healthcare provider can tell you if it is safe to take aripiprazole oral solution with your other medicines. Do not start or stop any medicines while taking aripiprazole oral solution without talking to your healthcare provider first. Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

How should I take aripiprazole oral solution?

- Take aripiprazole oral solution exactly as your healthcare provider tells you to take it. Do not change the dose or stop taking aripiprazole oral solution yourself.
- Aripiprazole oral solution can be taken with or without food.
- If you miss a dose of aripiprazole oral solution, take the missed dose as soon as you remember. If it is almost time for the next dose, just skip the missed dose and take your next dose at the regular time. Do not take two doses of aripiprazole oral solution at the same time.
- If you take too much aripiprazole oral solution, call your healthcare provider or poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.

What should I avoid while taking aripiprazole oral solution?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how aripiprazole oral solution affects you. Aripiprazole oral solution may make you drowsy.
- Avoid getting over-heated or dehydrated.
    - Do not over-exercise.
    - In hot weather, stay inside in a cool place if possible.
    - Stay out of the sun. Do not wear too much or heavy clothing.
    - Drink plenty of water.

What are the possible side effects of aripiprazole oral solution?
Aripiprazole oral solution may cause serious side effects, including:

- **See "What is the most important information I should know about aripiprazole oral solution?"**
- **Stroke in elderly people (cerebrovascular problems) that can lead to death**

- **Neuroleptic malignant syndrome (NMS).** Tell your healthcare provider right away if you have some or all of the following symptoms: high fever, stiff muscles, confusion, sweating, changes in pulse, heart rate, and blood pressure. These may be symptoms of a rare and serious condition that can lead to death. Call your healthcare provider right away if you have any of these symptoms.
- **Uncontrolled body movements (tardive dyskinesia).** Aripiprazole oral solution 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 aripiprazole oral solution. Tardive dyskinesia may also start after you stop receiving aripiprazole oral solution.
- **Problems with your metabolism such as:**
  - **High blood sugar (hyperglycemia) and diabetes.** Increases in blood sugar can happen in some people who take Aripiprazole oral solution. 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 start aripiprazole oral solution and during your treatment.

    Call your healthcare provider if you have any of these symptoms of high blood sugar while receiving aripiprazole oral solution:
    - 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.
- **Unusual urges.** Some people taking aripiprazole oral solution have had unusual urges, such as gambling, binge eating or eating that you cannot control (compulsive), compulsive shopping and sexual urges.

  If you or your family members notice that you are having unusual urges or behaviors, talk to your healthcare provider.
- **Orthostatic hypotension (decreased blood pressure).** Lightheadedness or fainting may happen when rising too quickly from a sitting or lying position.
- **Falls.** Aripiprazole oral solution may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position and can slow your thinking and motor skills which may lead to falls that can cause fractures or other injuries.
- **Low white blood cell count**
- **Seizures (convulsions)**
- **Problems with control of your body temperature especially when you exercise a lot or are in an area that is very hot. It is important for you to drink water to avoid dehydration.** See "What should I avoid while receiving aripiprazole oral solution?"
- **Difficulty swallowing that can cause food or liquid to get into your lungs.**

The most common side effects of aripiprazole oral solution in adults include:

- Nausea
- vomiting
- constipation
- headache
- dizziness
- anxiety
- insomnia
- restlessness

- blurred vision
- inner sense of restlessness/need to move (akathisia)
- upper respiratory illness

The most common side effects of aripiprazole oral solution in children include:

- feeling sleepy
- headache
- vomiting
- fatigue
- increased or decreased appetite
- increased saliva or drooling
- insomnia
- nausea
- stuffy nose
- weight gain
- uncontrolled movement such as restlessness, tremor
- muscle stiffness

These are not all the possible side effects of aripiprazole oral solution.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store aripiprazole oral solution?

- Store aripiprazole oral solution at room temperature, between 68°F to 77°F (20°C to 25°C).
- Opened bottles of Aripiprazole Oral Solution can be used for up to 6 months after opening, but not beyond the expiration date on the bottle.
- Aripiprazole oral solution is supplied in child-resistant bottles.

Keep aripiprazole oral solution and all medicines out of the reach of children.

General information about the safe and effective use of aripiprazole oral solution

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use aripiprazole oral solution for a condition for which it was not prescribed. Do not give aripiprazole oral solution to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about aripiprazole oral solution that was written for healthcare professionals.

What are the ingredients in aripiprazole oral solution?

Active ingredient: Aripiprazole, USP

Inactive ingredients:

Aripiprazole oral solution: disodium edetate, fructose, glycerin, malic acid, methylparaben, orange flavor, propylene glycol, propylparaben, sodium hydroxide, sucrose and purified water.

For more information about aripiprazole oral solution contact **Chartwell RX, LLC. at 1-845-232-1683**.

Manufactured for:
Chartwell RX, LLC.
Congers, NY 10920

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