

ARISA ORODISPERSIBLE TABLET

Aripiprazole (10mg, 15mg)

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What ARISA is used for

ARISA contain the active substance Aripiprazole and belong to a group of medicines called antipsychotics.

It is used to treat a disease characterized by symptoms such as hearing, seeing or sensing things which are not there, suspiciousness, mistaken beliefs, incoherent speech and behaviour and emotional flatness. People with this condition may also feel depressed, guilty, anxious or tense.

How ARISA works

ARISA works by acting on various receptors in the brain, particularly dopamine and serotonin receptor. ARISA is thought to work mainly by stabilizing dopamine activity in the brain

Before you use ARISA

- When you must not use it

Do not take ARISA

If you are allergic to aripiprazole or any of the other ingredients of this medicine

Pregnancy and lactation

Pregnancy

Do not take ARISA if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking ARISA, stop taking it immediately and contact your doctor.

Do not take ARISA if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

The following symptoms may occur in newborn babies, of mothers that have used ARISA in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or

weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Breastfeeding

Be sure to tell your doctor immediately if you are breast-feeding.

If you are taking ARISA, you should not breast-feed.

- Before you start use it

Talk to your doctor or pharmacist before taking ARISA if you

- Have or are at a risk of having diabetes (e.g.) being overweight or a family history of diabetes). Your doctor should check your blood sugar before you start taking ARISA and regularly during treatment
- a history of excessive gambling or other unusual urges (e.g. increased sexual urges, binge or compulsive eating, and compulsive shopping).
- Notice you are gaining weight, develop unusual movements, experience somnolence that interferes with normal daily activities, any difficulty in swallowing or allergic symptoms, please tell your doctor.
- Are an elderly patient suffering from dementia (loss of memory and other mental abilities). You or your caretaker/relative should tell your doctor if you have ever had a stroke or "mini" stroke.

Tell your doctor immediately if you are having any thoughts or feelings about hurting yourself. Suicidal thoughts and behavior have been reported during aripiprazole treatment.

Tell your doctor immediately if you suffer from muscle stiffness or inflexibility with high fever, sweating, altered mental status, or very rapid or irregular heartbeat.

ARISA contain aspartame
Patients who cannot take phenylalanine should note that ARISA contain aspartame, which is a source of phenylalanine. May be harmful for people with phenylketonuria.

ARISA contain maltose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

Blood pressure-lowering medicines: Aripiprazole may increase the effect of medicines used to lower the blood pressure. Be sure to tell your doctor if you take a medicine to keep your blood pressure under control.

Taking Arisa with some medicines may need to change your dose of Arisa. It is especially important to mention the following to your doctor:

- Medicines to correct heart rhythm
- Antidepressants or herbal remedy used to treat depression and anxiety
- Antifungal agents
- Certain medicines to treat HIV infection
- Anticonvulsants used to treat epilepsy

How to use ARISA

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommended dose for adults is 15 mg once a day. However, your doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day.

- When to use it

Use as directed by your doctor or pharmacist.

Try to take your ARISA at the same time each day. It does not matter whether you take it with or without food.

Do not open the blister until ready to administer. For single tablet removal, open the package and peel back the foil on the blister to expose the tablet. Do not push the tablet through the foil because this could damage the tablet.

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Immediately upon opening the blister, using dry hands, remove the tablet and place the entire tablet on the tongue. Tablet disintegration occurs rapidly in saliva. Arisa can be taken with or without liquid. Alternatively, disperse the tablet in water and drink the resulting suspension.

Even if you feel better, do not alter or discontinue the daily dose of Arisa without first consulting your doctor.

Do not stop your treatment just because you feel better. It is important that you carry on taking ARISA for as long as your doctor has told you to.

- How long to use it

Continue taking ARISA for as long as your doctor recommends.

If you have any further question on the use of this product, ask your doctor or pharmacist

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

If you miss a dose, take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you realize that you have taken more ARISA than your doctor has recommended, contact your doctor right away. If you cannot reach your doctor, go to the Emergency Department nearest to you and take the pack with you. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking ARISA.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give ARISA to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, ARISA can cause side effects, although not everybody gets them.

Talk to your doctor or pharmacist if you experience

- Increase in blood sugar level and/or symptoms of high blood sugar (e.g. increase thirst, increase hunger and frequent urination)
- Unpleasant leg sensation and an intense urge to move the legs (restless legs syndrome)
- Trouble breathing during (sleep apnoea)
- Difficulty or inability to pass urine (urinary retention)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Common side effects (may affect up to 1 in 10 people): diabetes mellitus, difficulty sleeping, feeling anxious, feeling restless and unable to keep still, difficulty sitting still, uncontrollable twitching, jerking or writhing movements, restless legs, trembling, headache, tiredness, sleepiness, light-headedness, shaking and blurred vision, decreased number of or difficulty making bowel movements, indigestion,

feeling sick, more saliva in mouth than normal, vomiting

Uncommon side effects (may affect up to 1 in 100 people): increased blood levels of the hormone prolactin, too much sugar in the blood, depression, altered or increased sexual interest, uncontrollable movements of mouth, tongue and limbs (tardive dyskinesia), muscle disorder causing twisting movements (dystonia), double vision, fast heartbeat, a fall in blood pressure on standing up which causes dizziness, light-headedness or fainting, hiccups.

Excessive gambling or other unusual urges, such as increased sexual urges, binge or compulsive eating, and compulsive shopping. If you or your family members notice that you are having unusual urges or behaviours, talk to your doctor or pharmacist.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers --> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of ARISA

- Storage

- Store below 30°C
- Keep this medicine out of the sight and reach of children.
- Store in the original package in order to protect from moisture.
- Do not store any medicine in the bathroom, or near a sink, or on a window sill
- Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.
- Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

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- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

ARISA 10 mg Orodispersible tablets are pink, round, biconvex tablets of 7.1mm in diameter, marked with "10" on one side.

ARISA 15 mg Orodispersible tablets are yellow, round, biconvex tablets of 8.1mm in diameter, marked with "15" on one side.

- Ingredients

- Active ingredient(s)

Active substance is aripiprazole.

Each orodispersible tablet of 10 and 15mg contains 10 and 15mg of aripiprazole respectively.

- Inactive ingredients

Other ingredients for 10 mg, are maltose, crospovidone, microcrystalline cellulose, silica colloidal anhydrous, croscarmellose sodium, xylitol, aspartame, red iron oxide (E172), talc, sodium stearyl fumarate, cherry powder and acesulfame potassium (flavouring agent).

Other ingredients for 15 mg orodispersible tablet are maltose, crospovidone, microcrystalline cellulose, silica colloidal anhydrous, croscarmellose sodium, xylitol, aspartame, yellow iron oxide (E172), talc, sodium stearyl fumarate, cherry powder and acesulfame potassium (flavouring agent).

- MAL number(s):

ARISA 10MG Orodispersible Tablets
MAL23056005AZ

ARISA 15MG Orodispersible Tablets
MAL23056006AZ

Manufacturer

Pharmathen International S.A.
Industrial Park Sapes,

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Greece

Product Registration Holder

Mansa Healthcare Sdn Bhd

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27 May 2024

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