

ARIPTOR TABLET

Aripiprazole Tablet USP (5 mg, 10mg, 15mg, 20 mg)

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What ARIPTOR is used for

ARIPTOR 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 ARIPTOR works

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

Before you use ARIPTOR

- When you must not use it:

Do not take ARIPTOR

- If you are allergic to Aripiprazole or any of the other ingredients of this medicine (listed in section "Ingredients").

Talk to your doctor before taking Aripiprazole if you suffer from:

- Seizure

- Involuntary, irregular muscle movements, especially in the face.
- Cardiovascular diseases, family history of cardiovascular disease, stroke or "mini" stroke, abnormal blood pressure
- Blood clots, or family history of blood clots, as antipsychotics have been associated with formation of blood clots
- Suicidal thoughts and behaviors have been reported during Aripiprazole treatment. Do not take ARIPTOR if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking ARIPTOR.

Pregnancy and Lactation

Pregnancy

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

The following symptoms may occur in newborn babies, of mothers that have used ARIPTOR in the last trimester (last three months of their pregnancy):

- Shaking.
- Muscle stiffness and/or weakness.
- Sleepiness.
- Agitation.
- Breathing problems.
- 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 ARIPTOR, you should not breast-feed.

- Before you start to use it

Talk to your doctor or pharmacist before taking ARIPTOR if you:

- Have a history of excessive gambling or other unusual urges (e.g. increased sexual urges, binge or compulsive eating, and compulsive shopping).
- 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 ARIPTOR and regularly during treatment
- 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.

- 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

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

- Medicines to correct heart rhythm eg quinidine
- Antidepressants or herbal remedy used to treat depression and anxiety
- Antifungal agents eg ketoconazole
- Certain medicines to treat HIV infection
- Anticonvulsants used to treat epilepsy
- Medicines that increase the level of serotonin: triptans, tramadol, tryptophan, SSRIs (such as paroxetine and fluoxetine), tricyclics (such as clomipramine, amitriptyline), pethidine, St John's Wort and venlafaxine. These medicines increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with Aripiprazole, you should see your doctor.

How to use ARIPTOR

- 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 15mg 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 ARIPTOR at the same time each day. It does not matter whether you take it with or without food.

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

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

- How long to use it

Continue taking ARIPTOR 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 ARIPTOR 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 the doctors, dentists and pharmacists that are treating you that you are taking ARIPTOR.
- 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 ARIPTOR 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 tablet make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Alcohol should be avoided when taking Aripiprazole.

Side effects

Like all medicines, ARIPTOR 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).

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- 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 effect 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.

Side effects may include:

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 ARIPTOR

- Storage

- Store below 30°C.
- Keep this medicine out of the sight and reach of children.
- Do not store any medicine in the bathroom, or near a sink, or on a windowsill.
- Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.
- Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer required. These measures will help to protect the environment.

Product description

- What it looks like

ARIPTOR TABLET 5 MG

White to off-white, round uncoated tablet debossed with “5” on one side and “17” on other side.

ARIPTOR TABLET 10 MG:

White to off-white, round uncoated tablets debossed with “10” on one side and “18” on other side.

ARIPTOR TABLET 15 MG:

White to off-white, round uncoated tablets debossed with “15” on one side and “19” on other side.

ARIPTOR TABLET 20 MG

White to off-white, round uncoated debossed with “20” on both sides.

ARIPTOR is available in blisters in cartons of 1 x 10 tablet, 3 x 10 and cartons of 10 x 10 tablet.

- Ingredients

Active ingredient

- Aripiprazole

Inactive ingredients

- Microcrystalline cellulose
- Colloidal silicone dioxide
- Mannitol 25
- Crospovidone XL 10
- Hydroxypropyl cellulose
- Magnesium stearate
- Purified water

- MAL number:

ARIPTOR TABLET 5 MG
MAL25106006AZ

ARIPTOR TABLET 10 MG
MAL18106045AZ

ARIPTOR TABLET 15 MG
MAL18106046AZ

ARIPTOR TABLET 20 MG
MAL25106007AZ

ARIPTOR TABLET

Aripiprazole Tablet USP (5 mg, 10mg, 15mg, 20 mg)

Manufacturer

Torrent Pharmaceuticals Limited
Ahmedabad-Mehsana Highway,
Indrad, Taluka Kadi, Dist. Mehsana,
Indrad, Gujarat 382721, India.

Product Registration Holder

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