

ARIP MTABLET

Aripiprazole (10 mg, 15 mg)

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What ARIP MT is used for

ARIP MT is indicated for the treatment of:-

- Schizophrenia (a severe brain disorder in which people interpret reality abnormally) and for maintenance of clinical improvement.
- Acute manic episodes (uncontrollable excitement that causes unusual behaviour) associated with bipolar 1 disorder (extreme mood swings ranging from episodes of depression to mania).

How ARIP MT works

Aripiprazole is thought to work by affecting the activity of some brain chemicals by adjusting the activities of both dopamine and serotonin. The exact mode of action of Aripiprazole's is not fully understood.

Before you use ARIP MT

- When you must not use it

If you are allergic (hypersensitive) to Aripiprazole or any of the other ingredients of Aripiprazole Tablet. (see section **Product Description**).

Pregnancy and lactation

Tell your doctor if you are pregnant, think that you may be pregnant or are planning to become pregnant. Do not take ARIP MT until you and your doctor have discussed the risks and benefits involved.

The following extrapyramidal and/or withdrawal symptoms may occur in newborn babies, of mothers that have used ARIP MT in the last trimester (last three months of their pregnancy):

- Agitation.
- Muscle stiffness and/or weakness.
- Shaking.
- Sleepiness.
- Breathing problems.
- Difficulty in feeding.

If your baby develops any of these symptoms you may need to contact your doctor.

Do not use this medicine if you are breast-feeding. This is because small amounts may pass into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breastfeeding.

- Before you start use it

Before treatment with Aripiprazole Tablet, tell your doctor if you suffer from:

- A reaction to some medicines called neuroleptic malignant syndrome (see section **Side Effect**).
- A reaction to some medicines called tardive dyskinesia (see section **Side Effect**).
- Low blood pressure.
- Problems with your heart or blood vessels.
- Problems with blood clots.
- Diabetes.
- Seizure (fits).
- Alzheimer's disease or dementia (loss of mental ability severe enough to interfere with normal daily activities).
- History of suicidal event.
- History of alcohol and/or drug abuse or dependence.

Talk to your doctor or pharmacist 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 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 ARIP MT and regularly during treatment.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Blood pressure-lowering medicines: Aripiprazole Tablet 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 Aripiprazole Tablet with some medicines may need to change your dose of Aripiprazole Tablet. It is especially important to mention the following to your doctor:

- Medicines to correct heart rhythm (e.g. quinidine).
- Antidepressants used to treat depression and anxiety (e.g. fluoxetine).
- Antifungal agents (e.g. ketoconazole).
- Anticonvulsants used to treat epilepsy (e.g. carbamazepine).

Other medicines not listed above may also interact with ARIP MT.

How to use ARIP MT

- How much to use

Schizophrenia:

The recommended starting and target dose for Aripiprazole is 10 or 15 mg/day administered on a once-a-day schedule without regard to meals.

Bipolar Mania:

Aripiprazole should be administered on a once-a-day schedule without regard to meals, generally starting at a dose of 15 to 30 mg/day. Dosage adjustments, if any, should occur at not before 24 hours interval.

The safety and efficacy of ARIP MT in patients under 18 years of age have not been established.

- When to use it

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

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- How long to use it

Do not stop taking your tablets just because you feel better. It is important that you carry on taking Aripiprazole Tablet for as long as your doctor tells you.

If you have any further questions 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.

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)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause:

- Lethargy.
- Increased blood pressure.
- Somnolence (sleepiness).
- Rapid heartbeat.
- Vomiting.

While you are using it

- Things you must do

Continue taking ARIP MT as long as your doctor tells you. If you have questions about how long to take ARIP MT, talk to your doctor or your pharmacist.

If you become pregnant while taking this medicine, tell your doctor immediately (see also Before you start to use it).

- Things you must not do

- You should not take this medicine when pregnant, unless you have discussed this with your doctor.
- If you are taking Aripiprazole Tablet, you should not breast-feed.

- Do not drink any alcohol if you have been given Aripiprazole Tablet.

- 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.

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

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

• **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.

• **Increased risk of death in elderly patients with dementia-related psychosis:**

- * Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Aripiprazole is not approved for the treatment of patients with dementia-related psychosis.

• **High blood sugar (hyperglycemia):**

- * Increases in blood sugar can happen in some people who take Aripiprazole Tablet.

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 Tablet and during therapy.

• **Difficulty swallowing:**

- * It may lead to aspiration and choking.

• **Tardive dyskinesia:**

- * Call your healthcare provider about any movements you cannot control in your face, tongue, or other body parts. These may be signs of a serious condition. Tardive dyskinesia may not go away, even if you stop taking Aripiprazole Tablet. Tardive dyskinesia may also start after you stop taking Aripiprazole Tablet.

• **Orthostatic hypotension (decreased blood pressure):**

- * Lightheadedness or fainting when rising too quickly from a sitting or lying position.

- Nausea.
- Vomiting.
- Constipation.
- Headache.
- Insomnia (inability to fall asleep).
- Dizziness.
- Restlessness.
- Inflammation of the pancreas.
- Chest pain.
- Sudden increase in body temperature.
- Sweating.
- Fast heartbeat.
- Muscle stiffness.
- Seizures (convulsions).
- Allergic reaction (rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body).
- 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

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that you are having unusual urges or behaviours, talk to your doctor or pharmacist.

Talk to your doctor or pharmacist if you experience:

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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Tell your doctor if you get any side effect that bothers you or that does not go away.

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

Storage and Disposal of ARIP MT

- Storage

- Store below 30°C. Protected from moisture

- 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

ARIP MT 10 TABLETS 10mg:

It is available as light yellow colored, round, flat, beveled edge uncoated tablets plain on the both side.

ARIP MT 15 TABLETS 15mg:

It is available as light yellow colored, round, flat, beveled edge, uncoated tablets plain on the both side.

- Ingredients

Active ingredient

- Aripiprazole.

Inactive ingredients

- Mannitol.
- Ferric oxide yellow.
- Colloidal silicon dioxide.
- Magnesium stearate.
- Citric acid monohydrate.
- Aspartame.
- Pineapple DC 254 flavour.
- Dragoco mango flavour.
- Crospovidone.
- Talc.

- MAL number(s):

ARIP MT 10 TABLETS 10mg:

MAL06071067AZ

ARIP MT 15 TABLETS 15mg:

MAL06071068AZ

Manufacturer

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Product Registration Holder

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