

# ARIP MT TABLETS

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 behavior) associated with Bipolar I 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**).
- Before you start to 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

## Pregnancy and breast feeding

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, and 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 breast-feeding.

- 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.

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- 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.

- 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 and 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,

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- Chest pain, sudden increase in body temperature, sweating, fast heart beat, muscle tiffness, 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).
- Inactive ingredients  
Mannitol  
Ferric oxide yellow  
Colloidal silicon dioxide  
Magnesium stearate  
Citric acid monohydrate  
Aspartame  
Pineapple DC 254 flavour  
Dragoco mango flavour  
Crospovidone  
Talc

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers →Reporting).

- MAL number(s):  
**ARIP MT 10 TABLETS 10mg:**  
MAL06071067A  
**ARIP MT 15 TABLETS 15mg:**  
MAL06071068A

## 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.

## Manufacturer

TORRENT PHARMACEUTICALS LTD.  
Indrad 382 721, District: Mehsana, INDIA.

## Product Registration Holder

MANSA PHARMA (M) SDN BHD  
Unit 502, Block C,  
Glomac Business Centre,  
10 Jalan SS6/1,  
47301 Kelana Jaya,  
Selangor.

## Product Description

- What it looks like  
**ARIP MT 10:**  
It is available as light yellow colored, round, flat, beveled edge uncoated tablets plain on the both side.  
**ARIP MT 15:**  
It is available as light yellow colored, round, flat, beveled edge, uncoated tablets plain on the both side.
- Ingredients
  - Active ingredient  
Aripiprazole

## Date of revision

06/10/2015

## Serial Number

BPFK(R4/1)061015/00336