

ARILIFT TABLETS

Aripiprazole (10mg, 15mg)

What is in this leaflet

1. What is ARILIFT used for
2. How ARILIFT works
3. Before you use ARILIFT
4. How to use ARILIFT
5. While you are using it
6. Side effects
7. Storage and Disposal of ARILIFT
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What ARILIFT is used for

ARILIFT 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 ARILIFT works

The exact way Aripiprazole works is not known but it attaches in the brain to receptors for two substances (neurotransmitters) called dopamine and serotonin (5HT), which are believed to play a role in schizophrenia and bipolar disorder. By attaching to these receptors it is thought that Aripiprazole helps normalize the activity of the brain, reducing psychotic or manic symptoms and preventing them from returning.

Before you use ARILIFT

- When you must not use it

Do not use ARILIFT if:

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

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, think that you may be pregnant or are planning to become pregnant. Do not take ARILIFT 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 ARILIFT 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 breast-feeding.

- Before you start to use it

Talk to your doctor or pharmacist 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 Arilift and regularly during treatment.
- Have a history of excessive gambling or other unusual urges (e.g. increased sexual urges, binge or compulsive eating, and compulsive shopping).

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

- Suicidality
- Cardiovascular disorders
- Conduction abnormalities
- Neuroleptic malignant syndrome (see section Side Effect).
- A reaction to some medicines called tardive dyskinesia (see section Side Effect).
- Seizure (fits)
- Hyperglycaemia and diabetes mellitus.
- Hypersensitivity
- Problems with your heart or blood vessels.
- Weight gain / Diabetes.
- Alzheimer's disease or dementia (loss of mental ability severe enough to interfere with normal daily activities).

- History of alcohol and/or drug abuse or dependence.
- Dysphagia
- Pathological gambling and other impulse control disorders.
- Lactose: Patients with rare hereditary problems of lactose intolerance.
- Patients with ADHD comorbidity

- 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.

Given the primary Central Nervous System effect of Aripiprazole, caution should be used when Aripiprazole is taken in combination with Alcohol or other CNS medicinal products with overlapping adverse reactions such as sedation.

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:

- A gastric acid blocker (e.g. famotidine)
- 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).

Valproate and Lithium : When either Valproate or lithium was administered concomitantly with aripiprazole, there was no clinically significant change in Aripiprazole concentrations.

Other medicines not listed above may also interact with ARILIFT.

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How to use ARILIFT

- How much to use

Schizophrenia:

The recommended starting dose is 10mg or 15mg administered once a day with or without meals. Maintenance dose is 15mg a day.

Bipolar Mania:

The recommended starting and target dose is 15mg administered once a day with or without meals. Can be increased to 30mg a day depending on patient's response. Dosage adjustment (if any) should not take place at intervals of not less than 24 hours.

Renal & Hepatic impairment : No dosage adjustment is required.

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

Elderly : No dosage adjustment is required for patients ≥65 years of age.

Gender : No dosage adjustment is required for female patients compared to male patients.

- 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, vomiting and diarrhoea.

While you are using it

- Things you must do

- Continue taking ARILIFT as long as your doctor tells you. If you have questions about how long to take ARILIFT, 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 behaviors 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):**
Light-headedness 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).

ARILIFT TABLETS

Aripiprazole (10mg, 15mg)

- 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).
- Increases 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)
- 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 behaviors, talk to your doctor or pharmacist.

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.

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.moh.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI)).

Storage and Disposal of ARILIFT

- Storage

Store below 30°C. Store in the original package.

- 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

ARILIFT 10MG Tablets:

It is available as Pink color, modified rectangular shaped, uncoated mottled tablets debossed with '252' on one side and plain on other side.

ARILIFT 15MG Tablets:

It is available as Yellow color, round shaped, beveled edge, uncoated mottled tablets debossed with '253' on one side and plain on other side.

- Ingredients

Active ingredient:

- *Aripiprazole.*

Inactive ingredients:

- *Lactose Monohydrate*
- *Microcrystalline cellulose*
- *Hydroxypropyl cellulose*
- *Maize Starch*
- *Crospovidone*
- *Colloidal Silicon Dioxide*
- *Pigment Blend PB-24880 Pink (Lactose monohydrate & Iron oxide Red)* (for strength 10mg)
- *Pigment Blend PB-52290 Yellow (Iron oxide Yellow & Lactose monohydrate)* (for strength 15mg)
- *Magnesium stearate*

- MAL number(s):

ARILIFT 10MG Tablets:

MAL20086011AZ

ARILIFT 15MG Tablets:

MAL20086012AZ

Manufacturer

Alembic Pharmaceuticals Limited
(Formulation Division)
Panelav, P.O. – Tajpura,
Taluka – Halol, District – Panchmahal,
Gujarat 389350, India

Product Registration Holder

GENPHARMA SDN. BHD.
Lot 5016, Jalan Teratai,
5 ½ Mile, Off Jalan Meru,
41050 Klang, Selangor.
Malaysia

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28/02/2025

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