

Proprietary name:	ARIPHRENTZ 5 mg; ARIPHRENTZ 10 mg, ARIPHRENTZ 15 mg and ARIPHRENTZ 30 mg
Dosage form:	Tablets
Active Ingredient:	Aripiprazole
Strength per dosage unit:	5 mg; 10 mg, 15 mg and 30 mg per tablet

1.3.2 PATIENT INFORMATION LEAFLET (FINAL)

SCHEDULING STATUS:

S5

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM:

Ariphrenz 5 mg Tablets

Ariphrenz 10 mg Tablets

Ariphrenz 15 mg Tablets

Ariphrenz 30 mg Tablets

Aripiprazole

Contains Sugar.

Ariphrenz 5 mg: Each tablet contains 66,80 mg of lactose monohydrate

Ariphrenz 10 mg: Each tablet contains 62,49 mg of lactose monohydrate

Ariphrenz 15 mg: Each tablet contains 93,40 mg of lactose monohydrate

Ariphrenz 30 mg: Each tablet contains 187,47 mg of lactose monohydrate

Please read this leaflet carefully before taking Ariphrenz.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare professional.
- **Ariphrenz** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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1. What **Aripiprazole** is and what it is used for
2. What you need to know before you take Aripiprazole
3. How to take **Aripiprazole**
4. Possible side effects
5. How to store **Aripiprazole**
6. Contents of the pack and other information

1. WHAT ARIPHRENZ IS AND WHAT IT IS USED FOR:

Aripiprazole contains the active substance aripiprazole and belongs to a group of medicines called antipsychotic.

Schizophrenia:

Aripiprazole is used to treat adults who suffer from a disease characterised 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.

Bipolar mania:

Aripiprazole is used to treat patients with a mental health condition that causes extreme mood swings that include emotional highs (mania or hypomania) and lows (depression), having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ARIPHRENZ:

Do not take Aripiprazole:

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

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- If you are under the age of 18

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking **Aripiprazole** tablets.

Warnings and special precautions

Take special care with Aripiprazole if:

- you are having any thoughts or feelings about hurting yourself (feeling suicidal),
- you have high blood sugar (characterised by the symptoms such as excessive thirst, passing of large amounts of urine, increase in appetite and feeling weak) or family history of diabetes,
- you get fits (seizures) since your doctor may want to monitor you more closely,
- you have involuntary, irregular muscle movements, especially in the face,
- you have cardiovascular disease (disease of the heart and circulation), family history of cardiovascular disease, stroke or “mini” stroke, abnormal blood pressure,
- you have blood clots, or family history of blood clots, as antipsychotics have been associated with formation of blood clots,
- you have experience with excessive gambling,
- you notice you are gaining weight, develop unusual movements, experience somnolence that interferes with normal daily activities, any difficulty in swallowing or allergic symptoms,
- you are an elderly patient suffering from dementia (loss of memory and other mental abilities),
- if you suffer from muscle stiffness or inflexibility with high fever, sweating, altered mental status, or very rapid or irregular heartbeat,

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If you notice that you are developing urges or cravings to behave in ways that are unusual for you, and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorder and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or preoccupation with an increase in sexual thoughts or feelings.

Aripiprazole may cause sleepiness, fall in blood pressure when standing up, dizziness and changes in your ability to move and balance, which may lead to falls. Caution should be taken, particularly if you are an elderly patient or have some debility.

If you have difficulty in eating or swallowing food or liquid (dysphagia), This could lead to tube feeding, with a resultant food and drink entering the lungs (referred to as aspiration). Aspiration could lead to risk of infection of the lungs (pneumonia).

Attention deficit-hyperactivity disorder (ADHD) often co-exists with bipolar disorder in adults. Caution should be taken in these patients when aripiprazole and stimulants, such as atomoxetine, are given together.

Your doctor may need to adjust or stop your dose.

Children and adolescents:

Do not use this medicine in children and adolescents under 18 years of age. It is not known if it is safe and effective in these patients.

Using other medicines with Aripiprazole:

Always tell your healthcare provider if you are taking any other medicine. (This includes all

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complementary or traditional medicines).

Always inform your doctor if you take any medication as this may interact with **Aripiprazole**.

Do not take the following list of medicines with Aripiprazole and tell your doctor if you are taking any of these:

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 **Aripiprazole** with some medicines may mean the doctor will need to change your dose of **Aripiprazole** or the other medicines. It is especially important to mention to your doctor if you are taking the following:

- medicines to correct heart rhythm (such as quinidine, amiodarone, flecainide),
- antidepressants or herbal remedy used to treat depression and anxiety (such as fluoxetine, paroxetine, venlafaxine, St. John's Wort),
- antifungal medicines (such as ketoconazole, itraconazole),
- certain medicines to treat HIV infection (such as efavirenz, nevirapine, protease inhibitors e.g. indinavir, ritonavir),
- anticonvulsants used to treat epilepsy (such as carbamazepine, phenytoin, phenobarbital),
- certain antibiotics used to treat tuberculosis (rifabutin, rifampicin),
- triptans (such as sumatriptan and zolmitriptan), tramadol and tryptophan used for conditions including depression, generalised anxiety disorder, obsessive compulsive disorder (OCD) and social phobia as well as migraine and pain,

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- SSRIs (such as paroxetine and fluoxetine) used for depression, OCD, panic and anxiety,
- other anti-depressants (such as venlafaxine and tryptophan) used in major depression,
- tricyclic's (such as clomipramine and amitriptyline) used for depressive illness,
- pain killers (such as tramadol and pethidine) used for pain relief.

Not all the medicines that may interact with Ariprenz are listed above.

Ariprenz with food and drink

Ariprenz can be taken with or without food and should be swallowed whole with a glass of water.

Alcohol should be avoided when taking this medicine.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or health care provider for advice before taking this medicine.

Safety of **Ariprenz** in pregnancy has not been established.

The following symptoms may occur in newborn babies of mothers that has **Ariprenz** during the last trimester (last 3 months of the pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding.

Safety of **Ariprenz** in breastfeeding mothers has not been established. Talk to your doctor if you intend on breastfeeding whilst taking **Ariprenz**.

Ariprenz is excreted in human milk.

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Driving and using machines:

Aripiprazole may cause sleepiness, feeling faint, blurred, and double vision.

It is not always possible to predict to what extent **Aripiprazole** may interfere with the daily activities of the patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **Aripiprazole** affects them.

Aripiprazole contains lactose monohydrate:

Aripiprazole tablets contain a sugar called lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking **Aripiprazole**.

3. HOW TO TAKE ARIPHRENZ

Do not share medicines prescribed for you with any other person. Always take **Aripiprazole** exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

The usual dose is as follows:

The recommended dose is 10 mg - 15 mg once a day with a maintenance dose of 15 mg daily with or without meals. Your doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day.

If you take more Aripiprazole than you should

In the event of overdose, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take Aripiprazole:

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If you forget to take your tablets, take them as soon as you remember. However, if it is nearly time for the next tablets, skip the missed tablets.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Aripiprazole:

Keep taking **Aripiprazole** tablets for as long as your doctor has told you. Do not stop your treatment just because you feel better.

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

4. POSSIBLE SIDE EFFECTS:

Aripiprazole can have side effects.

Not all side effects reported for Aripiprazole are included in this leaflet. Should your general health worsen while taking **Aripiprazole** please consult your doctor, pharmacist, or other healthcare professional for advice.

If any of the following happens, stop taking **Aripiprazole** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden signs of allergy such as rash, hives (also known as nettle rash or urticaria), severe irritation of your skin, swelling of the face, lips, tongue, or other parts of the body. These may be signs of a severe allergic reaction.
- Severe skin disorders with peeling and/or rashes with small pustules (with a fever) or blistering of the skin, mouth, eyes and genitals, with fever, chills, aching muscles and generally feeling unwell.
- A tingling sensation, numbness or weakness in your limbs.

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- Severe lack of appetite, feeling sick (nausea), being sick (vomiting), unusual, tiredness, stomach pain, muscle weakness, yellowing of your skin or whites of the eyes (jaundice), unusually dark urine, pale stools or hair loss. These may be signs of a liver problem.
- Shortness of breath, unexpected weight gain. Swelling of your legs or abdomen, feeling unusually tired or waking up short of breath at night. These may be signs of heart failure. Shortness of breath can also be a sign of fluid on the lungs.
- Serious diabetes complications, such as diabetic coma (a life threatening disorder that causes unconsciousness).
- Sudden unexplained death, heart stops beating (cardiac arrest).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side-effects:

- 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, weakness, sleepiness, light-headedness, shaking, blurred vision,
- Decreased number of or difficulty making bowel movements, indigestion, feeling sick, more saliva in mouth than normal, vomiting.

Less frequent side-effects

- Low levels of white blood cells, low levels of blood platelets, high blood sugar (diabetes), not enough sodium in the blood,
- Higher than normal blood levels of the hormone prolactin, decreased prolactin levels,
- Loss of appetite (anorexia),

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- Depression, altered or increased sexual interest, agitation, persistent, unwanted erection of the penis,
- Uncontrollable movements of mouth, tongue and limbs (tardive dyskinesia), muscle disorder causing twisting movements (dystonia), speech difficulty, double vision, sensitivity to light,
- Fast heartbeat, a fall in blood pressure on standing up which causes dizziness, high-headedness or fainting,
- Hiccups, infection of the lungs due to food or fluid (aspiration pneumonia),
- Liver failure, inflammation of the liver,
- Inflammation of the pancreas, difficulty swallowing foods and liquids, loose watery stool (diarrhoea),
- Allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching),
- Inability to regulate core body temperature, chest pain, swelling in your lower legs or hands,
- Increased blood pressure on standing.

Frequency unknown:

- Weight loss, weight gain,
- Thoughts of suicide, suicide attempt and suicide, feeling aggressive, agitation, nervousness, binge eating, compulsive shopping, tendency to wander away,
- Combination of fever, muscle stiffness, faster breathing, reduced consciousness and sudden changes in blood pressure and heart rate, fainting (neuroleptic malignant syndrome), seizure, serotonin syndrome (a reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk),
- Spasmodic movement of the eyeballs into fixed position, usually upward,
- Fast heart rhythm, abnormal heart rhythm, irregular slow heart rate,

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- Contraction of the vocal cords, abnormal contraction of the muscle on the throat, stomach pain,
- Hair loss, excessive sweating, heightened skin sensitivity to sunlight,
- Muscle injury, muscle pain, muscle stiffness,
- Loss of bladder control, difficulty in urinating,
- Withdrawal symptoms in newborn babies including shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding (see “Pregnancy and breastfeeding”),
- High blood pressure, loss of consciousness, clots in the veins.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE ARIPHREZ:

Store at or below 25 °C (room temperature).

Store in the original package until ready for use.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the medicine after the expiry date shown on the label or carton.

Return the expired medicine to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ariphrenz contains:

The active substance is aripiprazole.

The other ingredients are hydroxyl propyl cellulose, lactose monohydrate, magnesium stearate, maize starch, and microcrystalline cellulose.

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The tablets also contain the following colourants:

Aripiprazole 5 mg: FD & Blue No.2/ Indigo carmine

Aripiprazole 10 mg : iron oxide red

Aripiprazole 15mg : iron oxide yellow

Aripiprazole 30mg: iron oxide red

What Aripiprazole looks like and contents of the pack:

Aripiprazole 5 mg: Blue coloured, modified rectangular shaped uncoated tablets debossed with “ARI” on one side and “5” on other side.

Aripiprazole 10 mg: Pink coloured, modified rectangular shaped uncoated tablets debossed with “ARI” on one side and “10” on other side.

Aripiprazole 15 mg: Yellow coloured, round shaped uncoated tablets debossed with “ARI” on one side and “15” on other side.

Aripiprazole 30 mg: Pink coloured, round shaped uncoated tablets debossed with “ARI” on one side and “30” on other side.

Aripiprazole are packed in aluminium/ aluminium blister strip of 10 tablets and inserted in a printed cardboard carton.

Holder of Certificate of Registration

Ascend Laboratories (Pty) Ltd.

R21 Corporate Park,

121 Sovereign Drive, Block A, Office 202

Irene Ext. 30, Centurion,

0157

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This leaflet was last revised in

To be determined

Application Numbers:

Aripiprazole 5 mg: 530759.755

Aripiprazole 10 mg: 530760.756

Aripiprazole 15 mg: 530761.757

Aripiprazole 30 mg: 530762.758

Access to the corresponding Professional Information

The professional information will be included in each unit pack of the product.