

APO-ARIPIPRAZOLE TABLETS

Contains the active ingredient aripiprazole

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about aripiprazole. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Aripiprazole tablets. It contains the active ingredient aripiprazole.

It is used to treat schizophrenia.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, aripiprazole or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take

any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - a reaction to some medicines with a sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressure, which may lead to coma. This reaction is called neuroleptic malignant syndrome
 - a reaction to some medicines with abnormal movements of the tongue, or other uncontrolled movements of the mouth, tongue, cheeks or jaw which may progress to the arms and legs. This reaction is called tardive dyskinesia
 - low blood pressure
 - problems with your heart or blood vessels

- epilepsy, seizures or fits
- problems with your oesophagus (food pipe) such as difficulty in swallowing
- high blood sugar or diabetes mellitus
- Alzheimer's disease or dementia
- alcohol or drug abuse or dependence or a history of one of these
- venous thromboembolism or are at risk of venous thromboembolism.

Tell your doctor if you have past experience of excessive gambling.

3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breast-feed. Taking this medicine whilst breastfeeding is not recommended.
5. You are planning to have surgery.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with aripiprazole. These include:

- medicines for treating high blood pressure or heart problems (beta-blockers, calcium antagonists, ACE-inhibitors; anti-arrhythmics such as quinidine and amiodarone)
- medicines which can make you sleepy or alcohol
- fluoxetine, paroxetine or nefazodone, used for treating depression
- carbamazepine or phenytoin, used for epilepsy
- drugs for Parkinson's Disease

- ketoconazole, fluconazole or itraconazole - medicines used for fungal infections
- rifampicin, clarithromycin and erythromycin, used for treating bacterial infections
- efavirenz, nevirapine, ritonavir and indinavir, used for treating viral infections
- cyclosporin, used by patients who have had organ transplants, or who have rheumatoid arthritis or other rheumatic conditions
- cimetidine, used for treating stomach ulcers and other problems with the digestive tract
- St John's Wort, a herbal preparation used for mood
- grapefruit and grapefruit juice may affect the blood levels of aripiprazole in the body.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with aripiprazole.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablets whole with a glass of water. It does not matter if you take this medicine before or after food but try to be consistent each dose.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

The tablets are usually taken once a day, unless your doctor gives you different instructions.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you, unless you have any problems. In that case, check with your doctor. Aripiprazole tablets may control schizophrenia but they do not cure it so stopping them suddenly can mean your schizophrenia becomes uncontrolled. Improvements in symptoms may take some time to occur.

Make sure you have enough of this medicine to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident

and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Aripiprazole may cause some people to become drowsy or less alert than they are normally or cause lightheadedness, dizziness or

tiredness. If this occurs do not undertake the activity.

Be careful when drinking alcohol while you are being treated with this medicine. Your doctor may suggest you avoid alcohol while taking aripiprazole.

Make sure you keep cool in hot weather and keep warm in cool weather. Aripiprazole may affect the way your body reacts to temperature changes. It may prevent sweating, even during heatwaves. You may feel dizzy or faint if you are too hot.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking aripiprazole or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- headache
- indigestion
- nausea
- vomiting
- insomnia
- constipation
- light-headedness
- agitation
- anxiety
- inability to sit or stand still; restless movement of the arms and legs such as tapping, marching in places, rocking, crossing and uncrossing the legs
- weight gain
- weight loss
- loss of appetite
- excessive sweating
- drowsiness.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- feeling dizzy especially when getting up from a lying or sitting position
- high blood pressure
- chest pain
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- high blood sugar (excessive thirst, hunger and weakness) or the onset or worsening of diabetes
- speech disorder
- urinary incontinence
- difficulty swallowing.
- hiccups

Tell your doctor if you have obsessive (recurring) thoughts or behaviours or trouble controlling impulsive urges or while taking ABILIFY.

Obsessive compulsive behaviours (feeling the need to check things repeatedly or having certain thoughts repeatedly), gambling urges, sexual urges, compulsive spending, binge or compulsive eating and other urges have occurred in some patients

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- seizure, fits or convulsions
- fainting
- abnormal movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, or jaw which may progress to the arms and legs
- sudden increase in body temperature, sweating, fast heart beat, muscle stiffness, high blood pressure and convulsions
- rash
- muscle pain, muscle weakness or muscle stiffness

- inflammation of the pancreas, severe upper stomach pain often with nausea and vomiting
- disorder of body temperature regulation resulting in low body temperature or high body temperature
- painful irreversible erection
- difficulty in passing urine
- yellowing of the skin and/or eyes, also called jaundice with or without nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching and dark coloured urine
- serious lung infection with fever, chills, shortness of breath, cough, chest pain and blood streaked phlegm
- thoughts or talk about death or suicide; thoughts or talk about self-harm or doing harm to others; any recent attempts at self-harm; an increase in aggressive behaviour, irritability or agitation. If you or someone you know is showing these signs contact your doctor or a mental health advisor right away or go to the nearest hospital for treatment.

Other side effects not listed above may occur in some patients.

Also, while taking aripiprazole, some elderly patients with dementia have suffered serious side effects such as a "mini" stroke, stroke, pneumonia or heart problems. These serious side effects can be life threatening.

Allergic reactions

If you think you are having an allergic reaction to aripiprazole, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body

- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Aripiprazole Tablets look like

APO-Aripiprazole 2 mg:
Green, rectangular, slightly biconvex tablets, engraved "2" on one side, "A" on the other side.

APO-Aripiprazole 5 mg:
Blue, rectangular, slightly biconvex tablets, engraved "5" on one side, "A" on the other side..

APO-Aripiprazole 10 mg:
Pink, rectangular, slightly biconvex

tablets, engraved "10" on one side, "A" on the other side.

APO-Aripiprazole 15 mg:
Yellow, round, slightly biconvex tablets, engraved "ARI" over "15" on one side, "APO" on the other side.

APO-Aripiprazole 20 mg:
White to off-white, round, slightly biconvex tablets, engraved "ARI" over "20" on one side, "APO" on the other side.

APO-Aripiprazole 30 mg:
Pink, round, slightly biconvex tablets, engraved "ARI" over "30" on one side, "APO" on the other side.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

APO-Aripiprazole 2 mg: Each tablet contains 2 mg of aripiprazole as the active ingredient. It also contains the following inactive ingredients:

- Cellulose - Microcrystalline
- Tartaric Acid
- Magnesium Stearate
- Croscarmellose Sodium
- Indigo Carmine
- Iron Oxide Yellow.

APO-Aripiprazole 5 mg: Each tablet contains 5 mg of aripiprazole as the active ingredient. It also contains the following inactive ingredients:

- Cellulose - Microcrystalline
- Tartaric Acid
- Magnesium Stearate
- Croscarmellose Sodium
- Indigo Carmine.

APO-Aripiprazole 10 mg: Each tablet contains 10 mg of aripiprazole as the active ingredient. It also contains the following inactive ingredients:

- Cellulose - Microcrystalline
- Tartaric Acid
- Magnesium Stearate
- Croscarmellose Sodium
- Iron Oxide Red.

APO-Aripiprazole 15 mg: Each tablet contains 15 mg of aripiprazole as the active ingredient. It also

contains the following inactive ingredients:

- Cellulose - Microcrystalline
- Tartaric Acid
- Magnesium Stearate
- Croscarmellose Sodium
- Iron Oxide Yellow.

APO-Aripiprazole 20 mg: Each tablet contains 20 mg of aripiprazole as the active ingredient. It also contains the following inactive ingredients:

- Cellulose - Microcrystalline
- Tartaric Acid
- Magnesium Stearate
- Croscarmellose Sodium.

APO-Aripiprazole 30 mg: Each tablet contains 30 mg of aripiprazole as the active ingredient. It also contains the following inactive ingredients:

- Cellulose - Microcrystalline
- Tartaric Acid
- Magnesium Stearate
- Croscarmellose Sodium
- Iron Oxide Red.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

2mg:

APO-Aripiprazole 2 mg tablets
blister pack of 30 tablets:
AUST R 152903.

APO-Aripiprazole 2 mg tablets
bottles of 30 or 100 tablets:
AUST R 152917.

5 mg:

APO-Aripiprazole 5 mg tablets
blister pack of 30 tablets:
AUST R 152904.

bottles of 30 or 100 tablets:
AUST R 152911.

10 mg:

APO-Aripiprazole 10 mg tablets
blister pack of 30 tablets:
AUST R 152908.

bottles of 30 or 100 tablets:
AUST R 152920.

15 mg:

APO-Aripiprazole 15 mg tablets
blister pack of 30 tablets:
AUST R 152924.

bottles of 30 or 100 tablets:
AUST R 152898.

20 mg:

APO-Aripiprazole 20 mg tablets
blister pack of 30 tablets:
AUST R 152899.

bottles of 30 or 100 tablets:
AUST R 152932.

30 mg:

APO-Aripiprazole 30 mg tablets
blister pack of 30 tablets:
AUST R 152905.

bottles of 30 or 100 tablets:
AUST R 152929.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered trade marks of Apotex Inc.

This leaflet was last updated in February 2017