

Tevaripiprazole[®]

Aripiprazole 5mg, 10mg, 15mg, 20mg, 30mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tevaripiprazole. It does not contain all the available information. Some of the information contained in this leaflet may not apply to you.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Tevaripiprazole against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Tevaripiprazole is used for

Tevaripiprazole is a trade name (manufacturer's name) for the medicine aripiprazole (Ari-pip-rah-zol).

Aripiprazole belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

Tevaripiprazole is used to treat symptoms of schizophrenia.

Schizophrenia is a mental illness with disturbances in thinking, feelings and behaviour.

Your doctor may have prescribed aripiprazole for another reason. Ask your doctor if you have any questions

about why aripiprazole has been prescribed for you.

There is no evidence that aripiprazole is addictive.

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

Aripiprazole is not recommended for use in children under the age of 18, as safety and efficacy have not been established in this age group.

Before you take Tevaripiprazole

When you must not take it

Do not take Tevaripiprazole if you have an allergy to:

- aripiprazole
- any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction include:

- 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

Do not take Tevaripiprazole after the expiry or use by date printed on the pack.

If you take this medicine after this date has passed, it may not work as well.

Do not take Tevaripiprazole if the packaging is torn or shows signs of tampering.

If this is the case, return it to your pharmacist.

If you are not sure whether you should start taking Tevaripiprazole, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances such as foods, preservatives or dyes

Tell your doctor if you are pregnant or intend to become pregnant.

Tevaripiprazole is not recommended for use during pregnancy. If you need to take Tevaripiprazole during your pregnancy, your doctor will discuss with you the benefits and risks of taking it. Babies exposed to antipsychotics (including Tevaripiprazole) during the third trimester of pregnancy are at risk of experiencing shaking, muscle stiffness, difficulty in feeding and/or withdrawal symptoms. These symptoms may resolve spontaneously or require additional medical treatment.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

It is recommended that you do not breast-feed while taking Tevaripiprazole, as it may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Tell your doctor if 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
- lactose intolerance

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

Tell your doctor if you drink alcohol.

Your doctor may advise you to avoid alcohol as it can magnify the side effects of this medicine.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Tevaripirazole.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Tevaripirazole may interfere with each other. These include:

- medicines used to treat brain disorders such as, anxiety, depression, mood swings, epilepsy or seizures, Parkinson's disease or insomnia.
- medicines used to treat high blood pressure
- medicines used to treat fungal infections
- medicines used to treat heart rhythm disturbances
- medicines used to treat bacterial or viral infections
- a medicine called ciclosporin (Cysporin®; Neoral®; Sandimmun®)
- a medicine called cimetidine (Tagamet®; Magicul®; Sigmetadine®)

These medicines may be affected by Tevaripirazole, or may affect how well it works. Your doctor may need to adjust your dose of Tevaripirazole or of the other medicine.

Eating grapefruit or drinking grapefruit juice may affect how Tevaripirazole works.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking Tevaripirazole.

How to take Tevaripirazole

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how much you need to take each day. This will depend on your condition and whether you are taking any other medicines.

The label put on the carton by the pharmacist will tell you how much you should take.

If you do not understand the instructions on the carton, ask

your doctor or pharmacist for help.

How to take it

Tevaripirazole tablets should be swallowed whole and washed down with a glass of water.

Take Tevaripirazole at about the same time each day.

Unless your doctor gives you other directions, you should take Tevaripirazole only once a day.

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

It does not matter whether you take Tevaripirazole with or without food.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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 the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

How long to take it

Continue taking Tevaripirazole for as long as your doctor tells you.

Tevaripirazole helps to control your condition but does not cure it.

Therefore you must take Tevaripirazole every day.

Improvement in symptoms may take several days to some weeks to occur.

Even if you feel better do not stop taking Tevaripirazole unless your doctor tells you to.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 1126) or go to the Accident and Emergency Centre at your nearest hospital, if you or anyone else may have taken too much Tevaripiprazole. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Tevaripiprazole

Things you must do

Tell any doctors, dentists or pharmacists who are treating you that you are taking Tevaripiprazole.

If you are about to be started on any new medicine, tell your doctor, dentist and pharmacist that you are taking Tevaripiprazole.

If you plan to have any kind of surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Tevaripiprazole.

If you become pregnant while taking Tevaripiprazole, tell your doctor immediately.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not give Tevaripiprazole to anyone else, even if their symptoms seem similar or they have the same condition as you.

Do not take Tevaripiprazole to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking Tevaripiprazole or lower the dosage, even if you are

feeling better, without checking with your doctor.

If you stop taking Tevaripiprazole suddenly your condition may worsen.

Do not take more of this medicine and do not take it more often than your doctor has ordered.

Things to be careful of

Make sure that you know how you react to Tevaripiprazole before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light headed or not alert.

Tevaripiprazole may cause some people to become drowsy or less alert than they are normally or cause light-headedness, dizziness or tiredness. If this occurs do not undertake the activity.

If Tevaripiprazole makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

Getting up slowly may help.

Be careful when drinking alcohol while taking Tevaripiprazole.

Your doctor may suggest you avoid alcohol while you are being treated with Tevaripiprazole.

Make sure you keep cool in hot weather and keep warm in cool weather.

Tevaripiprazole 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. To stay cool in hot weather, try to do the following:

- wear light clothing
- spend time in air-conditioned environments (or keep windows open and use electric fans)
- drink plenty of water
- take cool baths or showers and avoid hot baths and saunas
- try to restrict exercise or heavy work to cool parts of the day

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tevaripiprazole.

Like other medicines Tevaripiprazole may cause some unwanted side effects. These are likely to vary from patient to patient. Tevaripiprazole is generally well-tolerated and the side effects are often hard to distinguish from disease symptoms. It is important that you tell your doctor as soon as possible about unwanted effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- headache
- indigestion
- nausea
- vomiting
- insomnia
- constipation
- light-headedness
- drowsiness
- 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.

These are the more common side effects of Tevaripiprazole

Tell your doctor if you notice the following side effects:

- feeling dizzy especially when getting up from a lying or sitting position
- altered or increased sexual interest

These side effects are uncommon.

- high blood sugar (excessive thirst, hunger and weakness) or the onset or worsening of diabetes

This side effect is rare.

- weight gain
- weight loss
- loss of appetite
- excessive sweating
- drowsiness
- high blood pressure
- chest pain
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- speech disorder
- urinary incontinence
- difficulty swallowing
- hiccups

These side effects are very rare.

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

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.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- seizure, fits or convulsions.
- fainting.
- abnormal movements of the tongue or other uncontrolled movements of the tongue, mouth, cheeks, eye or jaw which may progress to the arms and legs.
- sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, high blood pressure and convulsions.
- rash.
- 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) with or without fever

- 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.

These are very serious side effects.

You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any or only some of them.

After using Tevaripirazole

Storage

Store Tevaripirazole in a cool place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines. Do not keep outdated medicine or medicine no longer needed.

Disposal

If your doctor tells you to stop taking Tevaripirazole or the medicine has passed its expiry date, ask your pharmacist what to do with any leftover medicine.

Be sure that any discarded medicine is out of the reach of children.

Product Description

What it looks like

Tevaripirazole 5 mg uncoated tablet
- Light yellow coloured round flat faced bevelled edge tablet debossed '5' on one side and plain on the other side.

Tevaripirazole 10 mg uncoated tablet

- Pink to light pink coloured, oblong tablet with debossed '10' on one side and breakline on the other side.

Tevaripirazole 15 mg uncoated tablet

- Light yellow coloured, round flat faced bevelled edged tablets with debossed '15' on one side and breakline on the other side.

Tevaripirazole 20 mg uncoated tablet

- White to off white or pale cream coloured, capsule shaped biconvex table with debossed '20' on one side and breakline on the other side.

Tevaripirazole 30 mg uncoated tablet

- Pink to light pink coloured, round biconvex tablets with debossed '30' on one side and breakline on the other side.

Aripirazole tablets are packed in OPA/Al/PVC-Al blister in a carton. Each carton contains 30 tablets.

Ingredients

Active ingredient:

aripirazole

Other Ingredients:

- Lactose monohydrate
- Maize starch
- Microcrystalline cellulose
- Hyprollose
- Magnesium stearate
- Croscarmellose sodium

The following colorants are also present in the tablets:

- 5 mg - iron oxide yellow
- 10 mg - iron oxide red
- 15 mg - iron oxide yellow
- 20 mg - no colourants
- 30 mg - iron oxide red

Tevaripirazole does not contain sucrose, gluten, tartrazine or any other azo dyes.

Tevaripirazole contains sugars (as lactose).

Sponsored by

Teva Pharma Australia Pty Ltd
Level 1, 37 Epping Road
Macquarie Park NSW 2113
Australia

Australian Registration Numbers

5 mg tablets: AUST R 238013
10 mg tablets: AUST R 238014
15 mg tablets: AUST R 238032
20 mg tablets: AUST R 238033
30 mg tablets: AUST R 238034

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