

TEVARIPIRAZOLE®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using TEVARIPIRAZOLE?

TEVARIPIRAZOLE contains the active ingredient aripiprazole. TEVARIPIRAZOLE is used to treat symptoms of schizophrenia. For more information, see Section [1. Why am I using TEVARIPIRAZOLE?](#) in the full CMI.

2. What should I know before I use TEVARIPIRAZOLE?

Do not use if you have ever had an allergic reaction to TEVARIPIRAZOLE or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use TEVARIPIRAZOLE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TEVARIPIRAZOLE and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use TEVARIPIRAZOLE?

- Unless your doctor gives you other directions, you should take TEVARIPIRAZOLE only once a day.
- Take TEVARIPIRAZOLE at about the same time each day

More instructions can be found in Section [4. How do I use TEVARIPIRAZOLE?](#) in the full CMI.

5. What should I know while using TEVARIPIRAZOLE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using TEVARIPIRAZOLE.• If you become pregnant while taking TEVARIPIRAZOLE, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not give TEVARIPIRAZOLE to anyone else, even if their symptoms seem similar or they have the same condition as you.• Do not stop taking TEVARIPIRAZOLE or lower the dosage, even if you are feeling better, without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Make sure that you know how you react to TEVARIPIRAZOLE 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.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while taking TEVARIPIRAZOLE.• Your doctor may suggest you avoid alcohol while you are being treated with TEVARIPIRAZOLE.
Looking after your medicine	<ul style="list-style-type: none">• Store TEVARIPIRAZOLE in a cool place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using TEVARIPIRAZOLE?](#) in the full CMI.

6. Are there any side effects?

Common side effects are headache; indigestion; nausea; vomiting; insomnia; constipation; light-headedness; drowsiness; agitation; anxiety; inability to sit or stand still, restless movement of the arms and legs. Serious side effects include seizure; fits or convulsions; fainting; sudden increase in body temperature; sweating.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TEVARIPIRAZOLE®

Tablets

Active ingredient(s): *Aripiprazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TEVARIPIRAZOLE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TEVARIPIRAZOLE.**

Where to find information in this leaflet:

- [1. Why am I using TEVARIPIRAZOLE?](#)
- [2. What should I know before I use TEVARIPIRAZOLE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TEVARIPIRAZOLE?](#)
- [5. What should I know while using TEVARIPIRAZOLE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using TEVARIPIRAZOLE?

TEVARIPIRAZOLE contains the active ingredient **aripiprazole**. TEVARIPIRAZOLE is an antipsychotic agent which improves the symptoms of certain types of mental illness.

TEVARIPIRAZOLE 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.

2. What should I know before I use TEVARIPIRAZOLE?

Warnings

Do not use TEVARIPIRAZOLE if:

- you are allergic to aripiprazole, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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

Check with your doctor if you:

- have any other 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
 - have a history of or are at risk of sleep apnea (a sleep disorder where your breathing is interrupted during sleep)
 - lactose intolerance
- take any medicines for any other condition.
- have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.

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.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

TEVARIPIRAZOLE is not recommended for use during pregnancy. If you need to take TEVARIPIRAZOLE during your pregnancy, your doctor will discuss with you the benefits and risks of taking it. Babies exposed to antipsychotics (including TEVARIPIRAZOLE) 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with TEVARIPRAZOLE and affect how it works. 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 (Neoral®; Sandimmun®)
- a medicine called cimetidine (Tagamet®; Magicul®)

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

Eating grapefruit or drinking **grapefruit juice** may affect how TEVARIPRAZOLE works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TEVARIPRAZOLE.

4. How do I use TEVARIPRAZOLE?

How much to take / use

- TEVARIPRAZOLE tablets should be swallowed whole and washed down with a glass of water.
- It does not matter whether you take TEVARIPRAZOLE with or without food
- The label put on the carton by the pharmacist will tell you how much you should take.
- Follow the instructions provided and use TEVARIPRAZOLE until your doctor tells you to stop.
- Continue taking TEVARIPRAZOLE for as long as your doctor tells you. TEVARIPRAZOLE helps to control your condition but does not cure it. Therefore you must take TEVARIPRAZOLE every day. Improvement in symptoms may take several days to some weeks to occur. Even if you feel better do not stop taking TEVARIPRAZOLE unless your doctor tells you to.

When to take / use TEVARIPRAZOLE

- Take TEVARIPRAZOLE at about the same time each 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.

If you forget to use TEVARIPRAZOLE

TEVARIPRAZOLE should be used regularly at the same time each day.

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

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

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.

If you use too much TEVARIPRAZOLE

If you think that you have used too much TEVARIPRAZOLE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (In Australia by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TEVARIPRAZOLE?

Things you should do

Remind any doctor, dentist, pharmacist, surgeon or any other health professional you visit that you are using TEVARIPRAZOLE.

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

Call your doctor straight away if you:

- Become pregnant while taking ABILIFY

Things you should not do

- Do not give TEVARIPRAZOLE to anyone else, even if their symptoms seem similar or they have the same condition as you.
- Do not take TEVARIPRAZOLE to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking TEVARIPRAZOLE or lower the dosage, even if you are feeling better, without checking with your doctor. If you stop taking TEVARIPRAZOLE suddenly your condition may worsen.
- Do not take more of this medicine and do not take it more often than your doctor has ordered.

Hot or cool weather

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

TEVARIPIRAZOLE 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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TEVARIPIRAZOLE affects you.

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

Getting up slowly may help.

Drinking alcohol

Be careful when drinking alcohol while taking TEVARIPIRAZOLE.

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

Looking after your medicine

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

TEVARIPIRAZOLE 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 any unwanted effects.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • Indigestion • nausea • vomiting • constipation <p>Pain related:</p> <ul style="list-style-type: none"> • headache • chest pain <p>General well-being related:</p> <ul style="list-style-type: none"> • insomnia • 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. • feeling dizzy especially when getting up from a lying or sitting position • altered or increased sexual interest • high blood sugar (excessive thirst, hunger and weakness) or the onset or worsening of diabetes • weight gain • weight loss • loss of appetite • excessive sweating • drowsiness • high blood pressure • difficulty swallowing • hiccups <p>Infection related:</p> <ul style="list-style-type: none"> • frequent infections such as fever, severe chills, sore throat or mouth ulcers <p>Bleeding related:</p> <ul style="list-style-type: none"> • bleeding or bruising more easily than normal <p>Speech related</p> <ul style="list-style-type: none"> • speech disorder <p>Bladder related</p> <ul style="list-style-type: none"> • urinary incontinence 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Pain related:</p> <ul style="list-style-type: none"> • muscle pain, muscle weakness or muscle stiffness • painful irreversible erection <p>General well-being-related</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● seizure, fits or convulsions ● fainting ● abnormal movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, eyes 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 ● disorder of body temperature regulation resulting in low body temperature or high body temperature ● 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 <p>Allergy related</p> <ul style="list-style-type: none"> ● 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 <p>Inflammation related</p> <ul style="list-style-type: none"> ● inflammation of the pancreas, severe upper stomach pain often with nausea and vomiting <p>Infection related</p> <ul style="list-style-type: none"> ● serious lung infection with fever, chills, shortness of breath, cough, chest pain and blood streaked phlegm <p>Bladder related</p> <ul style="list-style-type: none"> ● difficulty in passing urine <p>Mental related</p> <ul style="list-style-type: none"> ● 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. 	<p>your nearest hospital if you notice any of these serious side effects.</p>

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 or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Also, while taking TEVARIPIRAZOLE, 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 else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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

You may not experience any or only some of them.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What TEVARIPIRAZOLE contains

Active ingredient (main ingredient)	Aripiprazole
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> ● Lactose monohydrate ● Maize starch ● Microcrystalline cellulose ● Hyprollose ● Magnesium stearate ● Croscarmellose sodium <p>The following colorants are also present in the tablets:</p> <ul style="list-style-type: none"> ● 5 mg - iron oxide yellow ● 10 mg - iron oxide red ● 15 mg - iron oxide yellow ● 20 mg - no colourants ● 30 mg - iron oxide red
Potential allergens	<p>TEVARIPIRAZOLE contains sugars (as lactose).</p> <p>TEVARIPIRAZOLE does not contain sucrose, gluten, tartrazine or any other azo dyes.</p>

Do not take this medicine if you are allergic to any of these ingredients.

What TEVARIPIRAZOLE 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.
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	AUST R 238013
TEVARIPIRAZOLE 10 mg uncoated tablet	Pink to light pink coloured, oblong tablet with debossed '10' on one side and breakline on the other side. AUST R 238014
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. AUST R 238032
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. AUST R 238033
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. AUST R 238034

Who distributes TEVARIPIRAZOLE

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park NSW 2113

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