

PHARMACOR POSACONAZOLE Modified Release Tablets

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 PHARMACOR POSACONAZOLE?

PHARMACOR POSACONAZOLE contains the active ingredient Posaconazole. Posaconazole is used to kill or stop the growth of fungi that can cause infections. For more information, see Section [1. Why am I using PHARMACOR POSACONAZOLE?](#) in the full CMI.

2. What should I know before I use PHARMACOR POSACONAZOLE?

Do not use if you have ever had an allergic reaction to Posaconazole 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 PHARMACOR POSACONAZOLE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PHARMACOR POSACONAZOLE 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 PHARMACOR POSACONAZOLE?

Do not switch between taking PHARMACOR POSACONAZOLE Modified Release tablets without talking to your doctor. Follow all directions given to you by your doctor and pharmacist carefully.

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

5. What should I know while using PHARMACOR POSACONAZOLE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using PHARMACOR POSACONAZOLE.• If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking POSACONAZOLE• If you need to have any blood tests, tell your doctor you are taking PHARMACOR POSACONAZOLE. PHARMACOR POSACONAZOLE may affect the results of some laboratory tests.
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if their condition seems similar to yours.• Do not use it to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• PHARMACOR POSACONAZOLE may cause dizziness, sleepiness, or blurred vision in some people.• There have been side effects reported with PHARMACOR POSACONAZOLE that may affect your ability to drive or operate machinery. Individual responses to PHARMACOR POSACONAZOLE may vary. Be careful before you drive or use any machines or tools until you know how PHARMACOR POSACONAZOLE affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store PHARMACOR POSACONAZOLE Modified Release tablets below 25 °C• Do not store PHARMACOR POSACONAZOLE or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.• Keep PHARMACOR POSACONAZOLE and all other medicines where children cannot reach them.

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

6. Are there any side effects?

Tell your doctor if you experience any of the following: loss of appetite, sleeplessness, headache, dizziness, sleepiness, tingling in fingers or toes, hot flushes, upset stomach, nausea, vomiting, stomach pain, diarrhoea, gas from stomach or bowel, dry mouth, altered sense of taste, dry skin, rash, itchiness, back pain, fever, raised blood pressure with a low potassium level.

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.

Consumer Medicine Information (CMI)

This leaflet provides important information about using PHARMACOR POSACONAZOLE. **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 PHARMACOR POSACONAZOLE.**

Where to find information in this leaflet:

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

1. Why am I using PHARMACOR POSACONAZOLE?

PHARMACOR POSACONAZOLE contains the active ingredient Posaconazole.

POSACONAZOLE is a medicine that belongs to the triazole group of antifungals. PHARMACOR POSACONAZOLE is used to kill or stop the growth of fungi that can cause infections.

PHARMACOR POSACONAZOLE Modified Release Tablets are used for:

- The treatment of invasive aspergillosis, a fungal infection caused by a fungus called **aspergillus**
- The treatment of other serious fungal infections called **fusariosis, zygomycosis, chromoblastomycosis and mycetoma.**

These types of fungal infections usually occur in some patients who may have lowered resistance to infection due to poor immunity.

Treatment of these serious fungal infections with PHARMACOR POSACONAZOLE is usually reserved for patients who do not respond to or cannot tolerate other medicines used to treat these types of fungal infections.

PHARMACOR POSACONAZOLE is also used to treat coccidioidomycosis, a rare and serious fungal infection.

PHARMACOR POSACONAZOLE is also used to prevent fungal infections, such as yeasts and moulds, from occurring in patients who are at high-risk of developing these infections.

Your doctor may have prescribed it for another reason.

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.

2. What should I know before I use PHARMACOR POSACONAZOLE?

Warnings

Do not use PHARMACOR POSACONAZOLE if:

you are allergic to posaconazole (or any other triazole antifungal medicines) or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include skin rash, itching, hives, shortness of breath, difficulty breathing, and swelling of the face, tongue or other parts of the body.

Check with your doctor if you:

have any allergies to any other medicines, including other antifungal medicines such as:

- itraconazole (Sporanox®)
- fluconazole (Diflucan®)
- voriconazole (Vfend®)
- ketoconazole (Nizoral®)

or any other substances such as foods, preservatives or dyes.

have or have ever had any other health problems/ medical conditions including:

- any kidney problems
- any liver problems
- any heart problems
- any problems with potassium, magnesium, or calcium levels in your blood.

Follow your doctor's advice if any blood tests to check on your kidney or liver are recommended

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?](#)

Children

PHARMACOR POSACONAZOLE is not recommended for children below the age of 13 years.

Pregnancy and breastfeeding

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

PHARMACOR POSACONAZOLE should not be taken during pregnancy unless indicated by your doctor. Women who are of childbearing potential should use effective contraception while taking PHARMACOR POSACONAZOLE and for 2 weeks after completing treatment.

Once you have finished taking PHARMACOR POSACONAZOLE, continue using contraception until your next period.

Your doctor will discuss the possible risks and benefits to you and your unborn baby.

If you become pregnant while you are taking PHARMACOR POSACONAZOLE, tell your doctor immediately.

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

PHARMACOR POSACONAZOLE should not be taken by breastfeeding women. The active ingredient, Posaconazole, may be passed into the breast milk. Your doctor can discuss the risks and benefits involved.

3. What if I am taking other medicines?

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

Do not take PHARMACOR POSACONAZOLE if you are taking any of the following medicines:

- certain medicines used to treat allergy or hay fever (terfenadine or astemizole)
- cisapride (a medicine used to treat certain stomach problems)
- pimozone (a medicine used to treat certain mental disorders)
- quinidine (a medicine used to treat irregular heart beat)
- ergotamine and dihydroergotamine, which are medicines used to treat migraine
- halofantrine (a medicine used to treat malaria)

- simvastatin, lovastatin, atorvastatin or similar medicines (called HMG-CoA reductase inhibitors or statins) that are used to treat high cholesterol levels.

Some medicines may interfere with PHARMACOR POSACONAZOLE and affect how it works.

Some medicines may increase the risk of side effects of PHARMACOR POSACONAZOLE by increasing the amount of posaconazole in the blood. Similarly, some medicines may decrease the effectiveness of PHARMACOR POSACONAZOLE by decreasing the amount of posaconazole in the blood.

Medicines that can decrease the effectiveness of PHARMACOR POSACONAZOLE are:

- rifabutin (used to treat tuberculosis)
- phenytoin (used to treat fits or convulsions)
- efavirenz and fosamprenavir (used to treat HIV infection)
- medicines used to decrease stomach acid such as cimetidine, ranitidine and omeprazole

PHARMACOR POSACONAZOLE may possibly increase the risk of side effects of some medicines by increasing the amount of these medicines in the blood. These include:

- vincristine, vinblastine and other vinca alkaloids (used to treat cancer)
- ciclosporin, tacrolimus and sirolimus (used to treat certain immune system problems or to prevent organ transplant rejection)
- rifabutin (used to treat certain infections)
- midazolam and other benzodiazepine medicines (used as sedatives or muscle relaxants)
- calcium channel blockers, such as diltiazem, nifedipine and verapamil (used in certain heart conditions and to treat high blood pressure)
- digoxin (used to treat certain heart conditions)
- sulfonylureas such as glipizide (used to treat diabetes)
- medicines used to treat HIV called protease inhibitors (including atazanavir which is given with ritonavir) and non- nucleoside reverse transcriptase inhibitors
- venetoclax (used to treat certain blood cancers)

These medicines may be affected by PHARMACOR POSACONAZOLE or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist will advise you.

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

4. How do I use PHARMACOR POSACONAZOLE?

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

This information may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, label, ask your doctor or pharmacist for help.

How much to take

For treatment and prevention of invasive fungal infections:

The usual dose is three tablets twice a day on the first day, then three tablets once a day, thereafter.

The dose may vary from one patient to another. Your doctor may recommend a different dose depending on your condition.

How to take it

Swallow the tablet whole with some water.

Do not crush, chew, break or dissolve the tablet.

PHARMACOR POSACONAZOLE modified release tablets may be taken with or without food.

How long to take it

Your doctor will advise how long you should take PHARMACOR POSACONAZOLE.

Continue taking PHARMACOR POSACONAZOLE for the length of time that your doctor recommends.

If you forget to take it

Take the dose you missed as soon as you remember, then continue to take it as you normally would.

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 that you missed.

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

If you take too much (overdose)

If you think that you have used too much Pharmacor Posaconazole you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia) 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 PHARMACOR POSACONAZOLE?

Things you should do

Always follow your doctor's instructions carefully.

If you are a woman of childbearing age, talk to your doctor about the need for effective contraception. Once you have finished taking Pharmacor Posaconazole, continue using contraception until your next period.

If you become pregnant while you are taking Pharmacor Posaconazole, tell your doctor immediately.

If you are about to start any other new medicine, tell your doctor that you are taking Pharmacor Posaconazole.

If you need to have any blood tests, tell your doctor you are taking Pharmacor Posaconazole. Pharmacor Posaconazole may affect the results of some laboratory tests.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Pharmacor Posaconazole.

Call your doctor straight away if you:

- Have diarrhoea or vomiting
- If you become pregnant or plan to get pregnant while you are taking Pharmacor Posaconazole.
- Do not feel well whilst are using Pharmacor Posaconazole, or after using Pharmacor Posaconazole
- mind any doctor, dentist or pharmacist you visit that you are using Pharmacor Posaconazole.

Remind any doctor, dentist or pharmacist you visit that you are using Pharmacor Posaconazole

Things you should not do

- Do not give Pharmacor Posaconazole to anyone else, even if they have the same condition as you.
- Do not use Pharmacor Posaconazole to treat any other medical complaints unless your doctor tells you to.

Driving or using machines

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

You may feel dizzy, sleepy, or have blurred vision whilst being given Pharmacor Posaconazole, which may affect your ability to drive or use tools or machines. If this happens, do not drive or use any tools or machines and contact your doctor.

Looking after your medicine

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

Do not take Pharmacor Posaconazole if the expiry date (EXP) printed on the pack has passed.

Store Pharmacor Posaconazole below 25°C. Store in original container.

Follow the instructions in the carton on how to take care of your medicine properly.

Store Pharmacor Posaconazole in a cool dry place away from moisture, heat or sunlight; for example, do **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

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

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.

Less serious side effects

Less serious side effects	What to do
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<ul style="list-style-type: none"> • Loss of appetite, upset stomach, nausea, vomiting, stomach pain, diarrhoea, gas from stomach or bowel, dry mouth, altered sense of taste • Sleeplessness, headache, dizziness, sleepiness, tingling in fingers or toes • Hot flushes • Raised blood pressure with a low potassium level (shown in blood test) • Dry skin, rash, itchiness • Back pain • Fever 	<p>Speak to your doctor if you have notice any of these less serious side effects and they worry you.</p>
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Rash, itchiness, hives • Swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing • Tingling or numbness of the hands or feet, or muscle weakness. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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.

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 leaflet was prepared in 05/2022

This medicine is only available with a doctor's prescription

What PHARMACOR POSACONAZOLE contains

Active ingredient (main ingredient)	PHARMACOR POSACONAZOLE contains 100mg of active POSACONAZOLE
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• hypromellose acetate succinate• microcrystalline cellulose• hypromellose• croscarmellose sodium• colloidal anhydrous silica• magnesium stearate• polyvinyl alcohol• Macrogol 3350• titanium dioxide• purified talc• iron oxide yellow

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

What PHARMACOR POSACONAZOLE looks like

PHARMACOR POSACONAZOLE Tablets are yellow coated, capsule shaped tablets with "100" marking on one side.

The Modified Release Tablets are packed in

- PVC/PCTFE (Aclar)/Al blister packs: 24's, 96's tablets
- HDPE bottle packs: 24's, 96's, 60's, 1000's tablets
- Bottle packs of 24, 60 and 96 tablets are packed with a child-resistant closure.
- Bottle pack containing 1000 tablets is for dispensing use only.

* Not all pack sizes may be available.

Who distributes PHARMACOR POSACONAZOLE

Pharmacor Pty Ltd.
CHATSWOOD, NSW 2067,
Australia

Australian Registration Numbers

Pharmacor Posaconazole Modified Release Tablet:

Bottle: AUST R 328101

Blister: AUST R 328104