

Posaconazole Sandoz®

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 Posaconazole Sandoz?

Posaconazole Sandoz 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 Posaconazole Sandoz?](#) in the full CMI.

2. What should I know before I use Posaconazole Sandoz?

Do not use Posaconazole Sandoz 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 Posaconazole Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Posaconazole Sandoz 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 Posaconazole Sandoz?

Follow all directions given to you by your doctor and pharmacist carefully. The dose may vary from one patient to another.

- Swallow the tablet whole with some water.
- Do not crush, chew, break or dissolve Posaconazole Sandoz tablet.
- Posaconazole Sandoz maybe taken with or without food.

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

5. What should I know while using Posaconazole Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Posaconazole Sandoz.• If you are about to start any other new medicine, tell your doctor that you are taking Posaconazole Sandoz.• If you need to have any blood tests, tell your doctor you are taking Posaconazole Sandoz. Posaconazole Sandoz may affect the results of some laboratory tests.
Things you should not do	<ul style="list-style-type: none">• Do not give Posaconazole Sandoz to anyone else, even if they have the same condition as you.• Do not use Posaconazole Sandoz to treat any other medical complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Posaconazole Sandoz may cause dizziness, sleepiness, or blurred vision in some people.• There have been side effects reported with Posaconazole Sandoz that may affect your ability to drive or operate machinery. Individual responses to Posaconazole Sandoz may vary. Be careful before you drive or use any machines or tools until you know how Posaconazole Sandoz affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store Posaconazole Sandoz tablet below 30°C• Do not store Posaconazole Sandoz and all other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.• Keep Posaconazole Sandoz and all other medicines where children cannot reach them.

For more information, see Section [5. What should I know while using Posaconazole Sandoz?](#) 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.

Posaconazole Sandoz[®]

Active ingredient(s): *posaconazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Posaconazole Sandoz. **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 Posaconazole Sandoz.**

Where to find information in this leaflet:

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

1. Why am I using Posaconazole Sandoz?

Posaconazole Sandoz contains the active ingredient posaconazole. Posaconazole Sandoz is a medicine that belongs to the triazole group of antifungals. Posaconazole is used to kill or stop the growth of fungi that can cause infections.

Posaconazole Sandoz is 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 Posaconazole Sandoz is usually reserved for patients who do not respond to or cannot tolerate other medicines used to treat these types of fungal infections.

Posaconazole Sandoz is also used to treat coccidioidomycosis, a rare and serious fungal infection.

Posaconazole Sandoz 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 Posaconazole Sandoz for another reason.

Ask your doctor if you have any questions about why Posaconazole Sandoz has been prescribed for you.

This medicine is available only with a doctor's prescription

2. What should I know before I use Posaconazole Sandoz?

Warnings

Do not use Posaconazole Sandoz if:

- you are allergic to posaconazole, 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 may include skin rash, itching, hives, shortness of breath, difficulty breathing, swelling of the face, tongue or other parts of the body.

Check with your doctor if you:

- Have any allergies to any other medicines or any other substances such as foods, preservatives or dyes, including other antifungal medicines such as:**
 - itraconazole
 - fluconazole
 - voriconazole
 - ketoconazole
- Have or have 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?](#)

Use in Children

Posaconazole Sandoz 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.

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

Once you have finished taking Posaconazole Sandoz, 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 Posaconazole Sandoz, tell your doctor immediately.

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

Posaconazole Sandoz should not be taken by breastfeeding women. It is possible that 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 medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not take Posaconazole Sandoz 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)
- pimozide (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 Posaconazole Sandoz and affect how it works.

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

Medicines that can reduce the effectiveness of Posaconazole Sandoz 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

Posaconazole Sandoz 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)
- cyclosporine, 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 Posaconazole Sandoz 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 Posaconazole Sandoz.

4. How do I use Posaconazole Sandoz?

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, 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 Posaconazole Sandoz

- Swallow the tablet whole with some water
- Do not crush, chew, break or dissolve the tablet.
- Posaconazole Sandoz may be taken with or without food.

How to long to take Posaconazole Sandoz

- Your doctor will advise how long you should take Posaconazole Sandoz
- Continue taking Posaconazole Sandoz for the length of time that your doctor recommends.

If you forget to take Posaconazole Sandoz

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 you missed.

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

If you have taken too much Posaconazole Sandoz

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

You should immediately:

- phone the Poisons Information Centre (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 Posaconazole Sandoz?

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 Posaconazole Sandoz, continue using contraception until your next period.
- If you become pregnant while you are taking Posaconazole Sandoz, tell your doctor immediately.
- If you are about to start any other new medicine, tell your doctor that you are taking Posaconazole Sandoz.
- If you need to have any blood tests, tell your doctor you are taking Posaconazole Sandoz. Posaconazole Sandoz may affect the results of some laboratory tests.
- Tell all doctors, dentists and pharmacists who are treating you that you are taking Posaconazole Sandoz.

Call your doctor straight away if you:

- Have diarrhoea or vomiting
- If you become pregnant or plan to get pregnant while you are taking Posaconazole Sandoz.
- Do not feel well whilst you are using Posaconazole Sandoz, or after using Posaconazole Sandoz

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

Things you should not do

- Do not give Posaconazole Sandoz to anyone else, even if they have the same condition as you.
- Do not use Posaconazole Sandoz 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 Posaconazole Sandoz affects you.

You may feel dizzy, sleepy, or have blurred vision whilst

being given Posaconazole Sandoz, 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 Posaconazole Sandoz if the packaging is torn or shows signs of tampering.
- Do not take Posaconazole Sandoz if the expiry date (EXP) printed on the pack has passed.

Store in original container.

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

Store it in a cool dry place below 30°C 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

If your doctor tells you to stop taking Posaconazole Sandoz, 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
Gut related <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	Speak to your doctor if you have any of these less serious side effects and they worry you.
Skin related <ul style="list-style-type: none">• dry skin, rash, itchiness	
Others <ul style="list-style-type: none">• sleeplessness, headache, dizziness, sleepiness, tingling in fingers or toes• hot flushes	

<ul style="list-style-type: none"> • raised blood pressure with a low potassium level (shown in blood test) • back pain • fever 	
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Do not take this medicine if you are allergic to any of these ingredients.

What Posaconazole Sandoz looks like

Posaconazole Sandoz 100 mg – yellow, oval, biconvex, film-coated tablet marked with “PS” on one side and “100” on the other side. Pack size of 24 tablets (Aust R 319352).

Serious side effects

Serious side effects	What to do
<p>Allergy related</p> <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 <p>Others</p> <ul style="list-style-type: none"> • 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>

Who distributes Posaconazole Sandoz

Sandoz Pty Ltd
 ABN 60 075 449 553
 54 Waterloo Road
 Macquarie Park, NSW 2113
 Tel: 1800 726 369

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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 medicine is only available with a doctor's prescription.

What Posaconazole Sandoz contains

Active ingredient (main ingredient)	Posaconazole
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • hypromellose acetate succinate • microcrystalline cellulose • hypromellose • silicon dioxide • croscarmellose sodium • magnesium stearate • polyvinyl alcohol • macrogol 3350 • titanium dioxide • purified talc • iron oxide yellow