

Consumer Medicine Information**WHAT IS IN THIS LEAFLET**

This leaflet answers some common questions about Posaconazole Sandoz. It does not contain all the available information.

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 Posaconazole Sandoz against the benefits this medicine is expected to have for you.

If you have any concerns about taking Posaconazole Sandoz, ask your doctor or pharmacist.

Read this leaflet carefully before taking Posaconazole Sandoz.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT POSACONAZOLE SANDOZ IS USED FOR

Posaconazole Sandoz contains the active ingredient, posaconazole. Posaconazole is a medicine that belongs to the triazole group of antifungal medicines.

Posaconazole Sandoz works by killing or stopping the growth of the fungi causing these 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.

BEFORE YOU TAKE POSACONAZOLE SANDOZ

When you must not take it

Do not take Posaconazole Sandoz if:

1. **you have an allergy to:**
 - Posaconazole or any other triazole antifungal medicines
 - any of the ingredients listed at the end of this leaflet (See Product Description)

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.

2. **you are pregnant or may become pregnant.**

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.

Posaconazole Sandoz is not recommended for children below the age of 13 years.

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.

If you take Posaconazole Sandoz after the expiry date has passed, it may not work (as well). Return this medicine to your pharmacist for disposal if it has expired or is damaged.

If you are not sure whether you should start taking Posaconazole Sandoz, take to your doctor.

Before you start to take it

Tell your doctor if:

1. **you have allergies to any other medicines, especially other antifungal medicines such as itraconazole, fluconazole, voriconazole, ketoconazole or any other substances such as foods, preservatives or dyes.**
2. **you 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.

3. **you are pregnant or plan 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. Your doctor will discuss the possible risks and benefit to your and your unborn baby.

4. **You are breastfeeding**

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.

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

Taking other medicines

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

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 decrease 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 are:

- 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

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 will advise you.

HOW TO TAKE POSACONAZOLE SANDOZ

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

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

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

Children

Posaconazole Sandoz is not recommended for children below the age of 13 years.

Posaconazole Sandoz

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 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 have missed.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Posaconazole Sandoz. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep these telephone numbers handy:

Poisons Information Centres:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

WHILE YOU ARE TAKING POSACONAZOLE SANDOZ

Things you must 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.

Things you must 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.

SIDE EFFECTS

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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 (shown in blood test)

If any of the following happen, stop taking Posaconazole Sandoz and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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.

These are very serious side effects. You may need urgent medical attention. These side effects are rare.

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

doctor if you notice anything else that is making you feel unwell.

AFTER TAKING POSACONAZOLE SANDOZ

Storage

- Store Posaconazole Sandoz below 30°C.
- Store in original container.

Do not store Posaconazole Sandoz or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Posaconazole Sandoz and all other medicines where children cannot reach them.

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 Posaconazole Sandoz, or if it has passed the expiry date, ask your pharmacist what to do with any left over medicine.

PRODUCT DESCRIPTION

What it looks like

Posaconazole Sandoz tablets are yellow, oval, film-coated tablets marked with "PS" on one side and "100" on the other side.

Posaconazole Sandoz tablets are available in blister packs of 24 tablets.

Ingredients

Each tablet contains 100 mg of posaconazole.

Other inactive ingredients are: hypromellose acetate succinate, microcrystalline cellulose, hypolose, silicon dioxide, croscarmellose sodium, magnesium stearate, OPADRY Yellow 85F220168.

Sponsor

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Australian Registration Number:
AUST R 319352

This leaflet was prepared in Dec 2019