

Posaconazole Devatis

Posaconazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Posaconazole Devatis. 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 Devatis against the benefits this medicine is expected to have for you.

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

Read this leaflet carefully before taking Posaconazole Devatis.

Keep this leaflet with the medicine.

You may need to read it again.

What Posaconazole Devatis is used for

Posaconazole Devatis is used for:

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

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

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

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

Posaconazole Devatis 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.

Posaconazole Devatis is a medicine which belongs to the triazole group of antifungal medicines.

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

Your doctor may have prescribed Posaconazole Devatis for another reason.

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

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

Before you take Posaconazole Devatis

When you must not take it

Do not take Posaconazole Devatis 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 Devatis if you are taking any of the following medicines:

- 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.
- 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

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

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

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

If you take Posaconazole Devatis 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 Devatis, talk to your doctor.

Before you start to take it

Tell your doctor if:

1. you have any allergies to any other medicines, especially other antifungal medicines such as itraconazole (Sporanox®), fluconazole (Diflucan®), voriconazole (Vfend®), ketoconazole (Nizoral®) 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

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 Devatis should not be taken during pregnancy unless indicated by your doctor. Women who are of childbearing potential should use effective contraception while taking Posaconazole Devatis. Your doctor can discuss the risks and benefits.

4. you are breastfeeding

Posaconazole Devatis 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.

5. you should avoid sun exposure while being treated. It is important to cover sun exposed areas of skin with protective clothing and use sunscreen with a high sun protection factor (SPF), as an increased sensitivity of skin to the sun's UV rays can occur.

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

Taking other medicines

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

Some medicines may interfere with Posaconazole Devatis. These include:

- warfarin, a medicine used to prevent blood clots
- rifabutin, a medicine used to treat tuberculosis
- phenytoin, a medicine used to treat fits or convulsions
- vinca alkaloids, used in the treatment of cancer
- cyclosporin, tacrolimus and sirolimus, used to treat certain immune system problems or to prevent organ transplant rejection
- midazolam and other benzodiazepine medicines used to treat anxiety or sleeplessness
- HMG-Co-A reductase inhibitors such as simvastatin, lovastatin and atorvastatin, which are used to lower cholesterol
- Calcium channel blockers, such as diltiazem, nifedipine and verapamil, used in certain heart conditions and to lower blood pressure
- Anti-retroviral medicines, such as efavirenz, atazanavir and ritonavir, used in the treatment of HIV.
- Digoxin, used to treat certain heart conditions
- Venetoclax, a medicine used to treat certain blood cancers.
- Flucloxacillin (antibiotic used against bacterial infections).

These medicines may be affected by Posaconazole Devatis 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.

Taking Posaconazole Devatis

Do not switch between taking Posaconazole Devatis Modified Release Tablets and Posaconazole Oral Suspension without talking to your doctor.

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 / bottle label, ask your doctor or pharmacist for help.

Children

Posaconazole Devatis is not recommended for children or adolescents below the age of 18 years for treatment of invasive fungal infections.

In high risk patients aged 13 years and older, Posaconazole Devatis may be given to prevent the development of invasive fungal infections.

How much to take

Treatment of invasive fungal infections (aspergillosis, coccidioidomycosis, fusariosis, zygomycosis chromoblastomycosis and mycetoma):

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 Devatis

- Swallow the tablet whole with some water.

- Do not crush, chew, break or dissolve the tablet.
- Posaconazole Devatis may be taken with or without food.

How long to take Posaconazole Devatis

Your doctor will advise how long you should take Posaconazole Devatis.

Continue taking Posaconazole Devatis 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 you have missed.

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

If you have taken too much (overdose)

Immediately telephone your doctor or Poisons Information Centre or go Casualty or Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Posaconazole Devatis. 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 Devatis

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

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

Things you must not do

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

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

Do not be alarmed by this list of possible 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
- Redness of the skin

If any of the following happen, stop taking Posaconazole Devatis and tell your doctor immediately or go to casualty 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 Devatis

Storage

Store below 30°C.

Do not store Posaconazole Devatis 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 Devatis 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 Devatis, 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 Devatis tablets are yellow colored, oblong, biconvex film-coated tablets.

Posaconazole Devatis tablets are available in blister packs of 24, 48 and 96 film-coated tablets. Not all pack sizes may be marketed.

Ingredients

Each tablet contains 100 mg of posaconazole

Other inactive ingredients are: hypromellose acetate succinate, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, hydroxypropylcellulose, magnesium stearate, polyvinyl alcohol, titanium dioxide, macrogol, talc, iron oxide yellow

Sponsor

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