

NOXAFIL® Modified Release Tablets and Oral Suspension

Posaconazole

Consumer Medicine Information

What is in this leaflet

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

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

Read this leaflet carefully before taking NOXAFIL.

Keep this leaflet with the medicine.

You may need to read it again.

What NOXAFIL is used for

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

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

NOXAFIL Modified Release Tablets and Oral Suspension 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.

NOXAFIL Oral Suspension is also used to treat superficial fungal infections of the mouth and throat called oropharyngeal candidiasis.

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

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

NOXAFIL 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 NOXAFIL for another reason.

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

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

Before you take NOXAFIL

When you must not take it

Do not take NOXAFIL 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 NOXAFIL 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.

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

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

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

If you take NOXAFIL 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 NOXAFIL, 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
 - 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**

NOXAFIL should not be taken during pregnancy unless indicated by your doctor. Women who are of childbearing potential should use effective contraception while taking NOXAFIL

and for 2 weeks after completing treatment. Your doctor will discuss the possible risks and benefits to you and your unborn baby.

4. **You are breastfeeding**

NOXAFIL 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 NOXAFIL.

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

Medicines that can decrease the effectiveness of NOXAFIL 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

NOXAFIL 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 NOXAFIL 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 NOXAFIL

Do not switch between taking NOXAFIL Modified Release Tablets and NOXAFIL 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

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

NOXAFIL Oral Suspension

Shake the bottle well before use.

How much to take

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

The usual dose for adults is 10 mL twice a day.

Treatment of oropharyngeal candidiasis:

The usual dose for adults is 5 mL once on the first day, then take 2.5mL once daily for 13 days.

Prevention of invasive fungal infections:

The usual dose for adults is 5 mL three times a day.

A measuring spoon is supplied with the medicine.

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

How to take NOXAFIL Oral Suspension

You should take NOXAFIL Oral Suspension with a meal or a nutritional supplement. Taking this medication with food containing fat will improve absorption.

Directions for opening the bottle

NOXAFIL Oral Suspension comes with a child-resistant cap. It can be opened by pushing down on the plastic screw cap while turning it anti-clockwise.

NOXAFIL Modified Release Tablets

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 NOXAFIL Modified Release Tablets

- Swallow the tablet whole with some water.
- Do not crush, chew, break or dissolve the tablet.
- NOXAFIL modified release tablets may be taken with or without food.

How long to take NOXAFIL

Your doctor will advise how long you should take NOXAFIL.

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

If you forget to take NOXAFIL

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 to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much NOXAFIL. 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 NOXAFIL

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

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

Things you must not do

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

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
- Raised blood pressure with a low potassium level (shown in blood test)

If any of the following happen, stop taking NOXAFIL 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 NOXAFIL

Storage

NOXAFIL Oral Suspension

- Keep NOXAFIL Oral Suspension in the bottle until it is time to take it.
- Keep NOXAFIL Oral Suspension in a cool dry place where the temperature stays below 25°C.
- Do not freeze NOXAFIL Oral Suspension.
- Protect NOXAFIL Oral Suspension from light.

NOXAFIL Modified Release Tablets

- Store NOXAFIL Modified Release Tablets below 30°C.
- Store in original container.

Do not store NOXAFIL 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 NOXAFIL 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 NOXAFIL, 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

NOXAFIL Oral Suspension

NOXAFIL Oral Suspension is a white liquid.

It is supplied in an amber glass bottle with a child-resistant cap. Each bottle contains 105 mL of suspension. A measuring spoon graduated to measure 2.5 mL and 5 mL is included with each bottle.

NOXAFIL Modified Release Tablets

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

NOXAFIL tablets are available in blister packs of 24 or 96 tablets.

Ingredients

NOXAFIL Oral Suspension

NOXAFIL Oral Suspension contains 40 mg posaconazole (the active ingredient) per mL of suspension.

Other inactive ingredients are polysorbate 80, simethicone, sodium benzoate, sodium citrate dihydrate, citric acid monohydrate, glycerol, xanthan gum, liquid glucose, titanium dioxide, artificial cherry flavouring, and purified water.

NOXAFIL Oral Suspension does not contain lactose, gluten, tartrazine or any other azo dyes.

NOXAFIL Modified Oral Release Tablets

Each tablet contains 100 mg of posaconazole.

Other inactive ingredients are: hypromellose acetate succinate, microcrystalline cellulose, hydroxypropylcellulose, silicon dioxide, croscarmellose sodium, magnesium stearate, polyvinyl alcohol, Macrogol 3350, titanium dioxide, purified talc, iron oxide yellow.

Sponsor

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Rd
Macquarie Park NSW 2113
Australia

Australian Registration Number:

Oral suspension AUST R 115556

Modified Release Tablet AUST R 216283

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