

NOXAFIL® Concentrated Injection

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 having NOXAFIL against the benefits this medicine is expected it will have.

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

Read this leaflet carefully.

Keep this leaflet.

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 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 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.

NOXAFIL is only for use in adults (18 years of age and older).

Before you are given NOXAFIL

When you must not be given it

You should not be given 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.**

3. 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.

Before you are given it

Tell your doctor, pharmacist or nurse 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. are taking midazolam, a hypnotic and sedative medicine.

4. you are pregnant or plan to become pregnant

NOXAFIL should not be used during pregnancy unless indicated by your doctor.

Women who are of childbearing potential should use effective contraception while being given NOXAFIL and for 2 weeks after completing treatment. Your doctor will discuss the possible risks and benefits to you and your unborn baby.

5. You are breastfeeding

NOXAFIL should not be given to 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, pharmacist or nurse about any of the above, tell them before you are given NOXAFIL.

Taking other medicines

Tell your doctor or pharmacist 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 these medicines or you may need to take different medicines. Your doctor or pharmacist will advise you.

How NOXAFIL is given

NOXAFIL concentrated injection will be diluted to the correct concentration by your pharmacist or nurse.

How much is given

The usual dose is 300 mg twice a day on the first day, then 300 mg once a day, thereafter.

How is it given

NOXAFIL is usually diluted and given as a slow infusion or "drip" injection into your vein (intravenously).

How long to take it

The length of treatment will depend on the type of infection you have and will be individually adapted for you by your doctor.

While you are given 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 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 have been given NOXAFIL.

Side effects

Tell your doctor, pharmacist or nurse as soon as possible if you do not feel well while you are being

given NOXAFIL or after 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, pharmacist or nurse to answer any questions you may have.

Tell your doctor or nurse if you experience any of the following:

- Feeling confused or weak
- Abnormal skin sensations, such as numbness, tingling, itching, creeping prickling or burning
- Swelling, redness and tenderness along the vein in which NOXAFIL was given
- Headache
- Loss of appetite
- Stomach pain or upset stomach, passing wind, dry mouth, changes in your taste
- Feeling weak, dizzy, tired or sleepy
- Rash
- Constipation, rectal discomfort

These are common side effects.

Tell your doctor or nurse or pharmacist immediately if you notice any of the following:

- **rash, itchiness, hives**
- **swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing**
- **nausea or vomiting, diarrhoea**
- **yellowing of your skin or whites of eyes, unusually dark urine or pale faeces, feeling sick for no reason, stomach problems, loss of appetite or unusual tiredness or weakness (signs of liver problems)**

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

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

Tell your doctor, pharmacist or nurse if you notice anything else that is making you feel unwell.

AUST R 218702

This leaflet was prepared in August 2017.

Based on PI dated 22 August 2017.

Storing NOXAFIL

Storage

NOXAFIL concentrated injection is stored in a refrigerator (2 to 8 degrees Celsius) in the pharmacy or on the ward in a hospital.

Once prepared, the product should be used immediately. If not used immediately it can be stored for up to 24 hours at 2 to 8 degrees Celsius (in a refrigerator).

NOXAFIL is for single use only and any unused solution should be discarded.

Product description

What it looks like

NOXAFIL concentrated injection is a clear, colourless to yellow liquid.

It is supplied as a single use vial closed with a bromobutyl rubber stopper and aluminium seal.

Ingredients

Active ingredient

- posaconazole 300 mg/16.7 mL.

Other ingredients are:

- sulfobutyl betadex sodium (SBECD)
- disodium edetate
- hydrochloric acid and sodium hydroxide for pH adjustment
- Water for Injections.

Sponsor

Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A,
26 Talavera Road
Macquarie Park NSW 2113
Australia

Australian Registration Number: