

Product Name: NOXAFIL 300 mg concentrate for solution for infusion	Component: English Patient Information Leaflet Date Approved: 17 September 2024
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SCHEDULING STATUS

S4

NOXAFIL® 300 mg concentrate for solution for infusion

Posaconazole

Read all of this leaflet carefully, before you are given NOXAFIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, or nurse or other healthcare provider.
- NOXAFIL concentrate for solution for infusion has been prescribed for you personally and you should not share your medicine with other.

people. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

What is in this leaflet

1. What NOXAFIL is and what it is used for
2. What you need to know before you use NOXAFIL

3. How to use NOXAFIL

4. Possible side effects

5. How to store NOXAFIL

6. Contents of the pack and other information

1. What NOXAFIL is and what it is used for

NOXAFIL contains a medicine called posaconazole. This belongs to a group of medicines called “antifungals”. NOXAFIL is used to prevent and treat many different fungal infections.

NOXAFIL works by killing or stopping the growth of some types of fungi that can cause infections.

NOXAFIL can be used to treat the following types of fungal infections in patients 18 years of age or older:

- Infections caused by fungi of the *Aspergillus* family that have not improved during treatment with the antifungal medicine’s amphotericin B, itraconazole or voriconazole, or when these medicines had to be stopped.
- Infections of the mouth or throat area caused by fungi of the *Candida* family that have not improved during treatment with the antifungal medicine’s amphotericin B, itraconazole or voriconazole, or when these medicines had to be stopped.
- Infections caused by fungi of the *Fusarium* family that have not improved during treatment of amphotericin B or other therapy, or when such therapy had to be stopped.

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- Infections caused by fungi that cause the conditions known as zygomycosis, cryptococcosis, chromoblastomycosis and mycetoma, that have not improved during treatment with itraconazole, or other therapy, or when such therapy had to be stopped.
- Infections caused by the condition known as coccidioidomycosis.
- NOXAFIL can be used to prevent fungal infections in patients whose immune systems may be weakened due to other medicines or diseases.

2. What you need to know before you take NOXAFIL

NOXAFIL should not be administered to you if:

- If you are hypersensitive (allergic) to posaconazole or to any of the other ingredients of NOXAFIL
- If you are taking medicines that contain ergot alkaloids (used to treat migraines). NOXAFIL can increase the blood levels of these medicines, which can lead to severe reductions in blood flow to some parts of the body and damage tissues
- If you are taking any of the following medicines. NOXAFIL can increase the blood levels of these medicines, which can lead to very serious disturbances in heart rhythm
 - terfenadine (used to treat allergies)
 - astemizole (used to treat allergies)
 - cisapride (used to treat stomach problems)
 - pimozide (used to treat symptoms of Tourette's disorder)
 - quinidine (used to treat abnormal heart rhythms)

- If you are taking simvastatin, lovastatin, atorvastatin and some similar medicines (called HMG-CoA reductase inhibitors or statins) that are used to treat high cholesterol levels in the blood
- If you are pregnant or breastfeeding.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before being given NOXAFIL if you:

have had an allergic reaction to another antifungal medicine such

- as ketoconazole, fluconazole, itraconazole or voriconazole
- have or have ever had liver problems. You may need to have blood tests while you are taking this medicine
- have an abnormal heart rhythm tracing (ECG) that shows a problem called long QTc interval
- have a weakness of the heart muscle or heart failure
- have a very slow heartbeat
- have heart rhythm disturbance
- have any problem with potassium, magnesium or calcium levels in your blood
- are taking vincristine, vinblastine and other “vinca alkaloids” (medicines used to treat cancer)
- are taking venetoclax (a medicine used to treat cancer).

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before being given NOXAFIL.

If you develop severe diarrhoea or vomiting (being sick) while taking NOXAFIL, talk to your doctor, pharmacist or nurse straight away, as this may stop it from working properly. See Section 4 for more information.

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Children

It is not recommended for children under the age of 18 years to take NOXAFIL 300 mg concentrate for solution for infusion.

Other medicines and NOXAFIL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes all complementary or traditional medicines.

NOXAFIL should not be given to you if you are taking any of the following:

- terfenadine (used to treat allergies)
- astemizole (used to treat allergies)
- cisapride (used to treat stomach problems)
- pimozide (used to treat symptoms of Tourette's and mental illness)
- quinidine (used to treat abnormal heart rhythms).

NOXAFIL can increase the amount of these medicines in the blood which may lead to very serious changes to your heart rhythm:

- any medicines that contain “ergot alkaloids” such as ergotamine or dihydroergotamine used to treat migraines. NOXAFIL can increase the amount of these medicines in the blood which may lead to a severe decrease in blood flow to your fingers or toes and could cause damage to them.

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- a “statin” such as simvastatin, atorvastatin or lovastatin used to treat high cholesterol.

NOXAFIL should not be given to you if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before being given this medicine

Other medicines

Look at the list of medicines given above that must not be taken while you are being given NOXAFIL.

In addition to the medicines named above there are other medicines that carry a risk of rhythm problems that may be greater when they are taken with NOXAFIL. Please make sure you tell your doctor about all the medicines you are taking (prescribed or non-prescribed).

Certain medicines may increase the risk of side effects of NOXAFIL by increasing the amount of NOXAFIL in the blood.

The following medicines may decrease the effectiveness of NOXAFIL by decreasing the amount of NOXAFIL in the blood:

- rifabutin and rifampicin (used to treat certain infections). If you are already taking rifabutin, you will need a blood test and you will need to look out for some possible side effects of rifabutin.
- some medicines used to treat or prevent fits including; phenytoin, carbamazepine, phenobarbital or primidone.
- efavirenz and fosamprenavir used to treat HIV infection.

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NOXAFIL may possibly increase the risk of side effects of some other medicines by increasing the amount of these medicines in the blood.

These medicines include:

- vincristine, vinblastine and other “vinca alkaloids” (used to treat cancer)
- venetoclax (used to treat cancer)
- ciclosporin (used during or after transplant surgery)
- tacrolimus and sirolimus (used during or after transplant surgery)
- rifabutin (used to treat certain infections)
- medicines used to treat HIV called protease inhibitors (including lopinavir and atazanavir, which are given with ritonavir)
- midazolam, triazolam, alprazolam or other “benzodiazepines” (used as sedatives or muscle relaxants)
- diltiazem, verapamil, nifedipine, nisoldipine or other “calcium channel blockers” (used to treat high blood pressure)
- digoxin (used to treat heart failure)
- Glipizide or other “sulfonylureas” (used to treat high blood sugar).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before being given NOXAFIL.

Pregnancy and breastfeeding

Tell your doctor if you are or think you are pregnant before you are given NOXAFIL. Do not take NOXAFIL if you are pregnant.

If you are a woman who could become pregnant you should use effective contraception while you are taking this medicine. If you become pregnant while you are taking NOXAFIL, contact your doctor straight away.

Do not breastfeed while taking NOXAFIL. This is because small amounts may pass into breast milk.

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Driving and using machinery

You may feel dizzy, sleepy, or have blurred vision while taking NOXAFIL, 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.

3. How to take NOXAFIL

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself NOXAFIL. It will be administered by a person qualified to do so.

If you take more NOXAFIL than you should

Since a health care provider will administer NOXAFIL, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the situation.

If a dose of NOXAFIL is missed

Since a healthcare provider will administer NOXAFIL, it is unlikely that a dose would be missed. However, tell your doctor or pharmacist if you think that a dose has been forgotten.

4. Possible side effects

Not all side effects reported for NOXAFIL are included in this leaflet.

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Should your general health worsen or if you experience any untoward effects while taking NOXAFIL, please consult your healthcare provider for advice.

Tell your doctor, pharmacist or nurse straight away if you notice any of the following serious side effects you may need urgent medical treatment:

- signs of liver problems, these include yellowing of your skin or whites of the eyes, unusually dark urine or pale faeces, feeling sick for no reason
- an increase in liver enzymes -shown up in blood tests
- low magnesium levels – shown up in blood tests
- water retention (oedema)
- a change in the salt level in your blood shown in blood tests signs include feeling confused or weak
- heart rhythm problems

Common (> 1/100, < 1/10) side effects:

- rash
- headache
- high blood pressure
- loss of appetite, stomach pain or upset stomach, passing wind, dry mouth, changes in your taste
- pain or an uncomfortable feeling in the upper middle part of your stomach area.
- fever with low white blood cell count (febrile neutropenia)
- feeling weak, dizzy, tired, or sleepy
- itching
- constipation
- rectal discomfort
- nausea or vomit (feeling or being sick), diarrhoea
- shivering
- swelling, redness, and tenderness along the vein in which NOXAFIL was given

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- low potassium levels – shown up in blood tests
- abnormal skin sensations, such as numbness, tingling, itching, creeping, pricking, or burning
- low phosphate levels – shown up in blood tests
- chest discomfort
- redness and sores of the lining of the mouth, lips, throat, stomach, and genitals
- swelling of the lungs or the major air passages of the lungs due to fungal infection
- acute renal failure: A condition when one or both of the kidneys suddenly stop working which can cause a build-up of waste that may require medical treatment or dialysis

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of NOXAFIL® 300 mg concentrate for solution for infusion.

5. How to store NOXAFIL 300 mg concentrate for solution for infusion

Store in a refrigerator at 2°C-8°C.

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From a microbiological point of view, once admixed, the product should be used immediately.

If not used immediately, the solution can be stored up to 24 hours refrigerated 2°C-8°C. This medicinal product is for single use only.

Store all medicines out of the reach of children.

6.Contents of the pack and other information

What NOXAFIL 300 mg concentrate for solution for infusion contains

Each vial contains 300 mg of posaconazole.

Each mL contains 18 mg of posaconazole.

The other ingredients are: Betadex Sulfobutyl Ether Sodium (SBECD)'Disodium edetate, Hydrochloric acid [for pH adjustment], Sodium hydroxide [for pH adjustment] and Water for injections.

What NOXAFIL 300 mg concentrate for solution for infusion looks like and contents of the pack

Type I tubing glass vial sealed with a closed with bromobutyl rubber stopper and capped with a flip-off seal.

Pack size: 1 vial(20 mL)

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Holder of Certificate of Registration

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