



Patient Information Sheet

Posaconazole (marketed as Noxafil)

This is a summary of the most important information about Noxafil. For details, talk to your healthcare professional.

What Is Noxafil?

Noxafil is a prescription medicine used in patients, 13 years and older, with weak immune systems to prevent serious *Candida* and *Aspergillus* fungal infections. Patients who are at risk of developing these serious fungal infections include those:

- with advanced HIV disease
- who have had stem cell transplants and have a disease called graft versus host disease (GVHD),
- who are undergoing chemotherapy for cancer treatment

Noxafil is also used to treat fungal infections in the mouth area (known as “thrush”) caused by fungi called *Candida*.

Noxafil has not been studied in children under the age of 13.

Who Should Not Take Noxafil?

You should not take Noxafil if you:

- take the following medicines:
 - migraine medicines called “ergot alkaloids”
 - terfenadine
 - astemizole
 - cisapride
 - pimozone
 - halofantrine
 - quinidine

If you are not sure about your medicines, talk to your doctor.

- are allergic to anything in Noxafil
- have an irregular heart rate
- cannot take a full meal or nutritional supplement

What Are The Risks?

The following are the major potential risks and side effects of Noxafil therapy.

Noxafil can cause serious problems such as:

- **drug interactions.** Noxafil can interact with many medicines and cause serious side effects including death. Sometimes the doses of your other medicines may need to be lowered or you may need to be checked more often. Know the medicines you take. Keep a list of them to show your healthcare professional.

- **allergic reaction.** You may have an allergic reaction to posaconazole or the other ingredients in Noxafil. Tell your healthcare professional if you ever had an allergic reaction to another antifungal medicine. Call your healthcare professional right away if you have any of the following symptoms of an allergic reaction:
 - rash
 - hives
 - redness of the skin
 - itching
 - shortness of breath
 - low blood pressure
- **liver damage.** Noxafil may cause damage to the liver. The risk of liver damage may be worsened when Noxafil is given to patients with serious medical conditions who are also taking several other medicines. Your healthcare professional may do blood tests to monitor your liver function at the start of treatment with Noxafil and during treatment with Noxafil.
- **irregular heart beat.** Noxafil may cause dangerous problems with your heart rhythm. Call your healthcare professional right away if you:
 - have fainted or lost consciousness
 - feel a change in the way your heart normally beats (palpitations)
- **Some common side effects that may occur with Noxafil include:**
 - liver problems
 - nausea or vomiting
 - diarrhea
 - fever
 - headache
 - low blood potassium
 - low white blood cell counts

You should report any new symptoms right away. This list of side effects is not complete. Ask your healthcare professional for more information.

What Should I Tell My Healthcare Professional?

Before you start taking Noxafil, tell your healthcare professional if you:

- are unable to eat full meals or take nutritional supplements. Noxafil is not absorbed well without food.





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- are taking cyclosporine (Neoral), tacrolimus (Prograf), or sirolimus (Rapamune). Noxafil can increase the levels of these drugs and cause adverse effects.
- have or had liver problems.
- are trying to become pregnant, are already pregnant, or are breast feeding. You and your health care professional will need to decide if Noxafil is right for you.
- have or had heart problems.
- have serious diarrhea or vomiting while on Noxafil.
- are taking any other medicines before you start taking Noxafil.
- have ever had an allergic reaction to other antifungal medicines such as ketoconazole, fluconazole, itraconazole, or voriconazole.

Tell your healthcare professional about all of the medicines you take.

Can Other Medicines Or Food Affect Noxafil?

Noxafil and many other medicines can interact with each other, sometimes causing serious side effects. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your healthcare professional. Do not take any new medicine while taking Noxafil unless your healthcare professional has told you it is okay.

Especially tell your healthcare professional if you take:

- cyclosporine (Neoral), tacrolimus (Prograf), or sirolimus (Rapamune)
- migraine or antispasmodic medications referred to as “ergot alkaloids.”
- certain chemotherapy medications referred to as

“vinca alkaloids”

- cimetidine
- rifabutin
- phenytoin
- halofantrine
- astemizole
- midazolam
- quinidine
- pimozide
- cholesterol lowering agents referred to as “statins.”
- certain blood pressure medications referred to calcium channel blockers

This is NOT a complete list. These medicines may affect how Noxafil works, or Noxafil may affect how these medicines work. Bring a list of all your medicines with you to show your healthcare professional.

How Do I Take Noxafil?

- Noxafil is a liquid suspension to be taken by mouth.
- Each dose of Noxafil should be taken with food or with a liquid nutritional supplement if you cannot eat food.
- Shake Noxafil well before use.

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