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PATIENT INFORMATION

# NOXAFIL<sup>®</sup>

## (posaconazole) ORAL SUSPENSION

Read the Patient Information that comes with NOXAFIL<sup>®</sup> Oral Suspension before you start taking it and each time you get a refill. There may be new information. This information does not replace talking with your doctor about your condition or treatment. Only your doctor can prescribe NOXAFIL and determine if it is right for you.

### **What is NOXAFIL<sup>®</sup>?**

- NOXAFIL is a prescription medicine that is used to prevent invasive fungal infections (infections that can spread throughout the body) caused by *Aspergillus* or *Candida* in patients with weak immune systems because of medicines or diseases [such as stem cell transplantation with graft-versus-host disease or chemotherapy for hematologic malignancy (blood cancers)].
  - NOXAFIL is also used to treat fungal infections in the mouth or throat area (known as “thrush”) caused by fungi called *Candida*. NOXAFIL can be used as initial treatment or as a treatment after itraconazole and/or fluconazole have failed.
- NOXAFIL is for adults and children over 13 years of age.

### **What should I tell my doctor before taking NOXAFIL<sup>®</sup>?**

Tell your doctor about all your health conditions, including if you:

- are taking certain drugs that suppress your immune system like **cyclosporine (Neoral<sup>®</sup>)**, **tacrolimus (Prograf<sup>®</sup>)**, or **sirolimus (Rapamune<sup>®</sup>)**. Serious and rare fatal toxicity from cyclosporine has occurred when taken in combination with posaconazole and, therefore, reduction of the dose of drugs like **cyclosporine**, **tacrolimus**, or **atazanavir** and frequent monitoring of drug levels of these medicines is necessary when taking them in combination with posaconazole.
- have ever had an allergic reaction to other antifungal medicines such as ketoconazole, fluconazole, itraconazole, or voriconazole.
- are taking any other medicines, including prescription and non-prescription medicines, vitamins, and herbal supplements.
- have, or have had liver problems. Your doctor may do blood tests to make sure you should take NOXAFIL.
- have, or have had an abnormal heart rate or rhythm.
- are, or think you are pregnant. Do not use NOXAFIL during pregnancy unless specifically advised by your doctor. You should use effective birth control while you are taking NOXAFIL if you are a woman who could become pregnant.

Contact your doctor immediately if you become pregnant while being treated with NOXAFIL.

Do not breastfeed while being treated with NOXAFIL, unless specifically advised by your doctor.

### **Who should not take NOXAFIL<sup>®</sup>?**

Do NOT take NOXAFIL if you are taking any of the medicines listed below.

If any of these medicines are taken together with NOXAFIL, serious or life-threatening side effects from these medicines, or a decrease in the effect of NOXAFIL can occur. Tell your doctor right away if you are taking any of these medicines:

- **sirolimus**
- ergot alkaloids (ergotamine, dihydroergotamine, methysergide, methylergonovine, ergonovine, or bromocriptine)
- terfenadine
- astemizole
- cisapride
- pimozone
- halofantrine
- quinidine
- rifabutin
- phenytoin
- cimetidine

If you have questions or are uncertain about your medicines, talk with your doctor or pharmacist.

Do not take NOXAFIL if you are allergic to anything in it. There is a list of what is in NOXAFIL at the end of this leaflet.

### **Can I take other medicines with NOXAFIL<sup>®</sup>?**

NOXAFIL and many medicines can interact with each other and some must not be taken together (see “**Who should not take NOXAFIL<sup>®</sup>?**”). The dose of other medicines may need to be adjusted when taken with NOXAFIL [for example, **cyclosporine (Neoral<sup>®</sup>)**, **tacrolimus (Prograf<sup>®</sup>)**, **ritonavir**, or **atazanavir**]. (See “**What should I tell my doctor before taking NOXAFIL<sup>®</sup>?**”)

Knowing the medicines that you are taking is important. **Tell your doctor** about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Keep a list of them with you to show your doctor or pharmacist. Do not take any new medicine without talking to your doctor.

### **What are possible side effects of NOXAFIL<sup>®</sup>?**

The most commonly reported side effects related to NOXAFIL use were nausea, diarrhea, vomiting, headache, stomach pain, bloating, liver problems, low blood potassium,

and decrease in neutrophils (certain type of white blood cells that fight infection).

**Rarely, NOXAFIL may cause serious or life-threatening side effects. It may also cause severe drug interactions as discussed above. Call your doctor right away if you have any of the symptoms listed below.**

Changes in heart rate or rhythm. People who have certain heart conditions or who take certain other medicines have a higher chance for this problem.

Rarely, very serious liver problems were reported in patients with serious underlying medical conditions. Your doctor may test your liver function while you are taking NOXAFIL. Call your doctor if you have any of these symptoms, as these may be signs of liver problems: you have itching, your eyes or skin turn yellow, you feel more tired than usual or feel like you have the flu, or you have nausea or vomiting.

Rarely, an increase in blood clots may occur in patients with blood cancers or post-stem cell transplantation. These events may or may not be further increased in patients also on posaconazole and primarily occurred in patients also receiving cyclosporine or tacrolimus. If you notice swelling of one leg or shortness of breath, notify your doctor immediately.

These are not all the side effects associated with NOXAFIL. For more information, ask your doctor or pharmacist. If you experience any unusual effects while taking NOXAFIL, contact your doctor immediately.

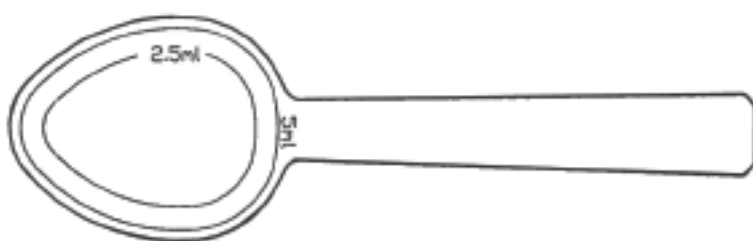
#### **How do I take NOXAFIL®?**

- NOXAFIL comes in cherry-flavored liquid form. Shake NOXAFIL Oral Suspension well before use.
- Take NOXAFIL for as long as your doctor tells you. Take each dose of NOXAFIL with a full meal, or with a liquid nutritional supplement if you are unable to eat a full meal.
- Follow your doctor's instructions on when and how much of NOXAFIL you should take.

If you miss a dose of NOXAFIL, take it as soon as you remember.

- If you take too much NOXAFIL, call your doctor or poison control center immediately.
- Tell your doctor right away if you develop severe diarrhea or vomiting.

A measured dosing spoon is provided, marked for doses of 2.5 mL and 5 mL.



It is recommended that the spoon is rinsed with water after each administration and before storage.

#### **How do I store NOXAFIL®?**

- Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature]. DO NOT FREEZE. Keep all containers tightly closed.
- **Keep NOXAFIL, as well as other medicines, out of the reach of children.**

#### **General information about NOXAFIL®**

Doctors can prescribe medicines for conditions that are not in this leaflet. Use NOXAFIL only as directed by your doctor. Do not give it to other people, even if they have the same symptoms as you. It may harm them.

This leaflet gives the most important information about NOXAFIL. For more information, talk to your doctor. You can ask your doctor or pharmacist for information about NOXAFIL that is written for health care professionals.

#### **What is in NOXAFIL®?**

Active ingredient: posaconazole.

Inactive ingredients: polysorbate 80, simethicone, sodium benzoate, sodium citrate dihydrate, citric acid monohydrate, glycerin, xanthan gum, liquid glucose, titanium dioxide, artificial cherry flavor, and purified water.

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**Rx only**

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