

Patient Information
Noxafil® (NOX-a-fil)
(posaconazole) injection
Noxafil® (NOX-a-fil)
(posaconazole) delayed-release tablets
Noxafil® (NOX-a-fil)
(posaconazole) oral suspension

What is Noxafil?

Noxafil injection, delayed-release tablets, and oral suspension are prescription medicines used to help prevent fungal infections that can spread throughout your body (invasive fungal infections). These infections are caused by fungi called *Aspergillus* or *Candida*. Noxafil is used in people who have an increased chance of getting these infections due to a weak immune system. These include people who have:

- had a hematopoietic stem cell transplantation (bone marrow transplant) with graft versus host disease
- a low white blood cell count due to chemotherapy for blood cancers (hematologic malignancy)

Noxafil oral suspension is also used to treat a fungal infection called “thrush” caused by *Candida* in your mouth or throat area. Noxafil oral suspension can be used as the first treatment for thrush, or as another treatment for thrush after itraconazole or fluconazole treatment has not worked.

Noxafil injection is for adults over 18 years of age. It is not known if Noxafil injection is safe and effective in children under 18 years of age.

Noxafil delayed-release tablets and oral suspension are for adults and children over 13 years of age.

It is not known if Noxafil oral suspension and delayed-release tablets are safe and effective in children under 13 years of age.

Who should not take Noxafil?

Do not take Noxafil if you:

- are allergic to posaconazole, any of the ingredients in Noxafil, or other azole antifungal medicines. See the end of this leaflet for a complete list of ingredients in Noxafil.
- are taking any of the following medicines:
 - sirolimus
 - pimozide
 - quinidine
 - certain statin medicines that lower cholesterol (atorvastatin, lovastatin, simvastatin)
 - ergot alkaloids (ergotamine, dihydroergotamine)

Ask your healthcare provider or pharmacist if you are not sure if you are taking any of these medicines.

Do not start taking a new medicine without talking to your healthcare provider or pharmacist.

What should I tell my healthcare provider before taking Noxafil?

Before you take Noxafil, tell your healthcare provider if you:

- are taking certain medicines that lower your immune system like cyclosporine or tacrolimus.
- are taking certain drugs for HIV infection, such as ritonavir, atazanavir, efavirenz, or fosamprenavir. Efavirenz and fosamprenavir can cause a decrease in the Noxafil levels in your body. Efavirenz and fosamprenavir should not be taken with Noxafil.
- are taking midazolam, a hypnotic and sedative medicine.
- are taking vincristine, vinblastine and other “vinca alkaloids” (medicines used to treat cancer).
- have or had liver problems.
- have or had kidney problems.
- have or had an abnormal heart rate or rhythm, heart problems, or blood circulation problems.
- are pregnant or plan to become pregnant. It is not known if Noxafil will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Noxafil passes into your breast milk. You and your healthcare provider should decide if you will take Noxafil or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Noxafil can affect the way other medicines work, and other medicines can affect the way Noxafil works, and can cause serious side effects.

Especially tell your healthcare provider if you take:

- rifabutin or phenytoin. If you are taking these medicines, you should not take Noxafil delayed-release tablets or Noxafil oral suspension.
- cimetidine or esomeprazole. If you are taking these medicines, you should not take Noxafil oral suspension.

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them with you to show your healthcare provider or pharmacist when you get a new medicine.

How will I take Noxafil?

- Do not switch between taking Noxafil delayed-release tablets and Noxafil oral suspension without talking to your healthcare provider.
- Take Noxafil exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much Noxafil to take and when to take it.
- Take Noxafil for as long as your healthcare provider tells you to take it.
- If you take too much Noxafil, call your healthcare provider or go to the nearest hospital emergency room right away.
- Noxafil injection is usually given over 30 to 90 minutes through a plastic tube placed in your vein.
- **Noxafil delayed-release tablets:**
 - Take Noxafil delayed-release tablets with food.
 - Take Noxafil delayed-release tablets whole. Do not break, crush, or chew Noxafil delayed-release tablets before swallowing. If you cannot swallow Noxafil delayed-release tablets whole, tell your healthcare provider. You may need a different medicine.
 - If you miss a dose, take it as soon as you remember and then take your next scheduled dose at its regular time. If it is within 12 hours of your next dose, do not take the missed dose. Skip the missed dose and go back to your regular schedule. Do not double your next dose or take more than your prescribed dose.
- **Noxafil oral suspension:**
 - Shake Noxafil oral suspension well before use.
 - Take each dose of Noxafil oral suspension during or within 20 minutes after a full meal. If you cannot eat a full meal, take each dose of Noxafil oral suspension with a liquid nutritional supplement or an acidic carbonated beverage, like ginger ale.
 - A measured dosing spoon comes with your Noxafil oral suspension and is marked for doses of **2.5 mL** and **5 mL**.
See Figure A.

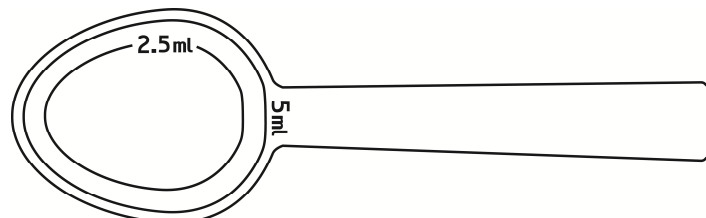


Figure A

- Rinse the spoon with water after each dose of Noxafil oral suspension and before you store it away.
- If you miss a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not take a double dose to make up for the forgotten dose.

Follow the instructions from your healthcare provider on how much Noxafil you should take and when to take it.

What are the possible side effects of Noxafil?

Noxafil may cause serious side effects, including:

- **drug interactions with cyclosporine or tacrolimus.** If you take Noxafil with cyclosporine or tacrolimus, your blood levels of cyclosporine or tacrolimus may increase. Serious side effects can happen in your kidney or brain if you have high levels of cyclosporine or tacrolimus in your blood. Your healthcare provider should do blood tests to check your levels of cyclosporine or tacrolimus if you are taking these medicines while taking Noxafil. Tell your healthcare provider right away if you have swelling in your arm or leg or shortness of breath.
- **problems with the electrical system of your heart (arrhythmias and QTc prolongation).** Certain medicines used to treat fungus called azoles, including posaconazole, the active ingredient in Noxafil, may cause heart rhythm

problems. People who have certain heart problems or who take certain medicines have a higher chance for this problem. Tell your healthcare provider right away if your heartbeat becomes fast or irregular.

- **liver problems.** Some people who also have other serious medical problems may have severe liver problems that may lead to death, especially if you take certain doses of Noxafil. Your healthcare provider should do blood tests to check your liver while you are taking Noxafil. Call your healthcare provider right away if you have any of the following symptoms of liver problems:
 - itchy skin
 - nausea or vomiting
 - yellowing of your eyes
 - feeling very tired
 - flu-like symptoms
- **increased amounts of midazolam in your blood.** If you take Noxafil with midazolam, Noxafil increases the amount of midazolam in your blood. This can make your sleepiness last longer. Your healthcare provider should check you closely for side effects if you take midazolam with Noxafil.

The most common side effects of Noxafil include:

- diarrhea
- nausea
- fever
- vomiting
- headache
- coughing
- low potassium levels in the blood

If you take Noxafil delayed-release tablets or Noxafil oral suspension, tell your healthcare provider right away if you have diarrhea or vomiting.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Noxafil. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Noxafil?

- Store Noxafil injection refrigerated at 36°F to 46°F (2°C to 8°C).
- Store Noxafil delayed-release tablets and oral suspension at room temperature between 68°F to 77°F (20°C to 25°C).
- **Do not** freeze Noxafil oral suspension.
- Safely throw away medicine that is out of date or no longer needed.

Keep Noxafil and all medicines out of the reach of children.

General information about the safe and effective use of Noxafil.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Noxafil for a condition for which it was not prescribed. Do not give Noxafil to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Noxafil that is written for health professionals.

What are the ingredients in Noxafil?

Active ingredient: posaconazole

Inactive ingredients:

Noxafil injection: Betadex Sulfobutyl Ether Sodium (SBECD), edetate sodium, hydrochloric acid, sodium hydroxide, and water for injection.

Noxafil delayed-release tablets: hypromellose acetate succinate, microcrystalline cellulose, hydroxypropylcellulose, silicon dioxide, croscarmellose sodium, magnesium stearate, and Opadry® II Yellow (consists of the following ingredients: polyvinyl alcohol partially hydrolyzed, Macrogol/PEG 3350, titanium dioxide, talc, and iron oxide yellow)

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

Manuf. for: Merck Sharp & Dohme Corp., a subsidiary of
 **MERCK & CO., INC., Whitehouse Station, NJ 08889, USA**

Injection: MSD International GmbH, Brinny, Innishannon, County Cork, Ireland
Delayed-Release Tablets: Manuf. by: N. V. Organon, Kloosterstraat 6, 5349 AB Oss, Netherlands
Oral Suspension: Manuf. by: Patheon Inc., Whitby, Ontario, Canada L1N 5Z5

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For more information, go to www.noxafil.com or call 1-800-672-6372.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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