

Patient Information

Posaconazole (poe" sa kon' a zole) Delayed-Release Tablets

What is posaconazole delayed-release tablets?

Posaconazole delayed-release tablets are prescription medicines used in adults and children 13 years of age and older to help prevent fungal infections that can spread throughout your body (invasive fungal infections). These infections are caused by fungi called *Aspergillus* or *Candida*. Posaconazole 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 or those with a low white blood cell count due to chemotherapy for blood cancers (hematologic malignancies).

Posaconazole delayed-release tablets are used for:

- prevention of fungal infections in adults and children 13 years of age and older.

It is not known if posaconazole delayed-release tablets are safe and effective in children under 2 years of age.

Who should not take posaconazole delayed-release tablets?

Do not take posaconazole delayed-release tablets if you:

- are allergic to posaconazole, any of the ingredients in posaconazole delayed-release tablets, or other azole antifungal medicines. See the end of this leaflet for a complete list of ingredients in posaconazole delayed-release tablets.
- are taking any of the following medicines:
 - o sirolimus
 - o pimozide
 - o quinidine
 - o certain statin medicines that lower cholesterol (atorvastatin, lovastatin, simvastatin)
 - o ergot alkaloids (ergotamine, dihydroergotamine)
- have chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and you have just started taking venetoclax or your venetoclax dose is being slowly increased.

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 posaconazole delayed-release tablets?

Before you take posaconazole delayed-release tablets, 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 posaconazole levels in your body. Efavirenz and fosamprenavir should not be taken with posaconazole delayed-release tablets.
- are taking midazolam, a hypnotic and sedative medicine.
- are taking vincristine, vinblastine and other "vinca alkaloids" (medicines used to treat cancer).
- are taking venetoclax, a medicine 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 posaconazole delayed-release tablets will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if posaconazole passes into your breast milk. You and your healthcare provider should decide if you will take posaconazole delayed-release tablets 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. Posaconazole can affect the way other medicines work, and other medicines can affect the way posaconazole 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 posaconazole delayed-release tablets.

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 posaconazole delayed-release tablets?

- **Do not switch between posaconazole oral suspension and posaconazole delayed-release tablets.**
- Take posaconazole delayed-release tablets exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much posaconazole delayed-release tablets to take and when to take it.
- Take posaconazole delayed-release tablets for as long as your healthcare provider tells you to take it.
- If you take too many posaconazole delayed-release tablets, call your healthcare provider or go to the nearest hospital emergency room right away.
- Take posaconazole delayed-release tablets with or without food.
- Take posaconazole delayed-release tablets whole. Do not break, crush, or chew posaconazole delayed-release tablets before swallowing. If you cannot swallow posaconazole 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.

Follow the instructions from your healthcare provider on how much posaconazole delayed-release tablets you should take and when to take it.

What are the possible side effects of posaconazole delayed-release tablets?

Posaconazole delayed-release tablets may cause serious side effects, including:

- **drug interactions with cyclosporine or tacrolimus.** If you take posaconazole delayed-release tablets 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 posaconazole delayed-release tablets. 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 posaconazole delayed-release tablets, 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.
- **changes in body salt (electrolytes) levels in your blood.** Your healthcare provider should check your electrolytes while you are taking posaconazole delayed-release tablets.
- **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 posaconazole delayed-release tablets. Your healthcare provider should do blood tests to check your liver while you are taking posaconazole delayed-release tablets. 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 or skin
 - feeling very tired
 - flu-like symptoms
- **increased amounts of midazolam in your blood.** If you take posaconazole delayed-release tablets with midazolam, posaconazole 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 posaconazole delayed-release tablets.

The most common side effects of posaconazole delayed-release tablets in adults include:

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

If you take posaconazole delayed-release tablets, 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 posaconazole delayed-release tablets. 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 posaconazole delayed-release tablets?

- Store posaconazole delayed-release tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Safely throw away medicine that is out of date or no longer needed.

Keep posaconazole delayed-release tablets and all medicines out of the reach of children.

General information about the safe and effective use of posaconazole delayed-release tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use posaconazole delayed-release tablets for a condition for which it was not prescribed. Do not give posaconazole delayed-release tablets 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 posaconazole delayed-release tablets that is written for health professionals.

What are the ingredients in posaconazole delayed-release tablets?

Active ingredient: posaconazole

Inactive ingredients:

hypromellose acetate succinate, microcrystalline cellulose, hydroxypropylcellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, polyvinyl alcohol partially hydrolyzed, titanium dioxide, macrogol/polyethylene glycol 3350, talc and iron oxide yellow.

Additional Pediatric Use information is approved for Merck Sharp & Dohme Corp.'s NOXAFIL (posaconazole) delayed-release tablets. However, due to Merck Sharp & Dohme Corp.'s marketing exclusivity rights, this drug product is not labeled with that pediatric information.

Manufactured for:

Chartwell RX, LLC
Congers, NY 10920

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For more information, call 1-845-232-1683.

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

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