

Voriconazole (vor" i kon' a zole), tablets

Read the Patient Information that comes with voriconazole before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your condition or treatment.

What is voriconazole?

Voriconazole is a prescription medicine used to treat certain serious fungal infections in your blood and body. These infections are called “aspergillosis,” “esophageal candidiasis,” “*Scedosporium*,” “*Fusarium*,” and “candidemia”.

It is not known if voriconazole is safe and effective in children younger than 12 years old.

Who should not take voriconazole?

Do not take voriconazole if you:

- **are allergic to voriconazole or any of the ingredients in voriconazole.** See the end of this leaflet for a complete list of ingredients in voriconazole.
- **are taking any of the following medicines:**
  - cisapride (Propulsid®)
  - pimozone (Orap®)
  - quinidine (like Quinaglute®)
  - sirolimus (Rapamune®)
  - rifampin (Rifadin®)
  - carbamazepine (TegretoI®)
  - long-acting barbiturates like phenobarbital (Luminal®)
  - efavirenz (Sustiva®)
  - ritonavir (Norvir®)
  - rifabutin (Mycobutin®)
  - ergotamine, dihydroergotamine (ergot alkaloids)
  - St. John’s Wort (herbal supplement)

Ask your healthcare provider or pharmacist if you are not sure if you are taking any of the medicines listed above. Do not start taking a new medicine without talking to your healthcare provider or pharmacist.

What should I tell my healthcare provider before taking voriconazole?

- Before you take voriconazole, tell your healthcare provider if you:
- have or ever had heart disease, or an abnormal heart rate or rhythm. Your healthcare provider may order a test to check your heart (EKG) before starting voriconazole.
  - have liver or kidney problems. Your healthcare provider may do blood tests to make sure you can take voriconazole.
  - have trouble digesting dairy products, lactose (milk sugar), or regular table sugar. Voriconazole tablets contain lactose.
  - are pregnant or plan to become pregnant. Voriconazole can harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant. Women who can become pregnant should use effective birth control while taking voriconazole.
  - are breast-feeding or plan to breast-feed. It is not known if voriconazole passes into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take voriconazole.

**Tell your healthcare provider about all the medicines you take**, including prescription and non-prescription medicines, vitamins and herbal supplements.

Voriconazole may affect the way other medicines work, and other medicines may affect how voriconazole works.

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

How should I take voriconazole?

- **Voriconazole may be prescribed to you as:**
  - Voriconazole tablets
- Take voriconazole tablets exactly as your healthcare provider tells you to.
- Take voriconazole tablets at least 1 hour before or at least 1 hour after meals.
- If you take too much voriconazole, call your healthcare provider or go to the nearest hospital emergency room.


What should I avoid while taking voriconazole?

- You should not drive at night while taking voriconazole. Voriconazole can cause changes in your vision such as blurring or sensitivity to light.
- Do not drive or operate machinery, or do other dangerous activities until you know how voriconazole affects you.
- Avoid direct sunlight. Voriconazole can make your skin sensitive to the sun and the light from sunlamps and tanning beds. You could get a severe sunburn. Use sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight. Talk to your healthcare provider if you get sunburn.

What are possible side effects of voriconazole?

Voriconazole may cause serious side effects including:

- **liver problems.** Symptoms of liver problems may include:
  - itchy skin
  - yellowing of your eyes
  - feeling very tired
  - flu-like symptoms
  - nausea or vomiting

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- **vision changes.** Symptoms of vision changes may include:
  - blurred vision
  - changes in the way you see colors
  - sensitivity to light (photophobia)
- **serious heart problems.** Voriconazole may cause changes in your heart rate or rhythm, including your heart stopping (cardiac arrest).
- **allergic reactions.** Symptoms of an allergic reaction may include:
  - fever
  - sweating
  - feels like your heart is beating fast (tachycardia)
  - chest tightness
  - trouble breathing
  - feel faint
  - nausea
  - itching
  - skin rash
- **kidney problems.** Voriconazole may cause new or worse problems with kidney function, including kidney failure. Your healthcare provider should check your kidney function while you are taking voriconazole. Your healthcare provider will decide if you can keep taking voriconazole
- **serious skin reactions.** Symptoms of serious skin reactions may include:
  - rash or hives
  - mouth sores
  - blistering or peeling of your skin
  - trouble swallowing or breathing

Call your healthcare provider or go to the nearest hospital emergency room right away if you have any of the symptoms listed above.

**The most common side effects of voriconazole include:**

- vision changes
- rash
- vomiting
- nausea
- headache
- fast heart beat (tachycardia)
- hallucinations (seeing or hearing things that are not there)
- abnormal liver function tests

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 voriconazole. 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 voriconazole?**

- Store voriconazole tablets at room temperature, 59° to 86° F (15° to 30°C). Do not refrigerate or freeze.
- Keep voriconazole tablets in a tightly closed container.
- Safely throw away medicine that is out of date or no longer needed.
- **Keep voriconazole, as well as all other medicines, out of the reach of children.**

**General information about the safe and effective use of voriconazole**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use voriconazole for a condition for which it was not prescribed. Do not give voriconazole to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about voriconazole. If you would like more information, talk to your healthcare provider. You can ask your healthcare provider or pharmacist for information about voriconazole that is written for health professionals.

**What are the ingredients of voriconazole?**

Active ingredient: voriconazole

Inactive ingredients:

**Voriconazole tablets:** lactose monohydrate, pregelatinized starch (maize starch), croscarmellose sodium, povidone, magnesium stearate, and a coating containing hypromellose (HPMC 2910), titanium dioxide, lactose monohydrate, and triacetin

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