

- darkening of the skin on the stomach, thighs, breasts, and arms
- bruising easily
- excessive hair growth
- thinning skin
- high blood sugar
- excessive sweating

Inflammation of the pancreas (pancreatitis). Symptoms of pancreatitis may include pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen to your back. The pain may happen with or without vomiting.

Bone problems. Voriconazole may cause weakening of bones and bone pain. Tell your healthcare provider if you have bone pain.

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 in adults include:

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

The most common side effects of voriconazole in children include:

- stomach pain
- diarrhea
- low blood potassium levels
- abnormal liver function tests
- low blood pressure
- low blood calcium levels
- low blood magnesium levels
- vision changes
- rash
- fast heart beat (tachycardia)
- vomiting
- nausea

Other possible side effects include:

- bleeds
- high blood pressure
- low platelet counts
- inflammation of mucous membranes
- constipation
- high blood sugar levels
- low blood phosphate levels
- headache
- fullness of the stomach area
- swelling in the arms and legs
- hallucinations (seeing or hearing things that are not there)
- upper respiratory tract infection
- coughing up blood
- dizziness
- kidney problems

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. 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 oral suspension at room temperature between 59°F to 86°F (15°C to 30°C). Do not refrigerate or freeze.
- Voriconazole oral suspension should be thrown away (discarded) after 14 days.
- Keep voriconazole oral suspension 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- Safely throw away medicine that is out of date or no longer needed.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.

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 oral suspension: colloidal silicon dioxide, titanium dioxide, xanthan gum, sodium citrate dihydrate, sodium benzoate, anhydrous citric acid, natural and artificial orange flavor, and sucrose

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

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Assembly Instructions

CHECK WITH YOUR PHARMACIST TO ENSURE VORICONAZOLE FOR ORAL SUSPENSION HAS BEEN RECONSTITUTED (i.e. is in liquid form).

To open, push down on bottle cap while twisting cap counterclockwise. Remove cap from bottle.

Push bottle adapter ALL THE WAY into bottle top (if pharmacist has not done so). Once bottle adapter is inserted, leave in place.

SHAKE CLOSED BOTTLE FOR APPROXIMATELY 10 SECONDS BEFORE EACH USE.

Insert oral dispenser into bottle top.

Holding the bottle with one hand, push down on oral dispenser plunger to push air into bottle.

Turn bottle upside down and pull back oral dispenser plunger. Draw prescribed dose of medicine into oral dispenser.

Remember to leave the bottle adapter in the bottle and put the cap back on the bottle. Store at room temperature.

IMPORTANT: Adapter must be fully inserted prior to use. Pull back on oral dispenser plunger to prescribed dose.

Insert oral dispenser into bottle top.

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High-dose Rivaroxaban (15 mg every 12 hours) and Low-dose Rivaroxaban (10 mg every 12 hours) are contraindicated with Voriconazole.

Proton Pump Inhibitors (PPIs) such as Pantoprazole, Rabeprazole, and Esomeprazole are contraindicated with Voriconazole.

Anticoagulants such as Warfarin, Apixiban, and Rivaroxaban are contraindicated with Voriconazole.

Antifungals such as Fluconazole, Isavuconazole, and Anidulafungin are contraindicated with Voriconazole.

Antibiotics such as Rifampin, Rifabutin, and Linezolid are contraindicated with Voriconazole.

Antivirals such as Acyclovir, Valacyclovir, and Foscarnet are contraindicated with Voriconazole.

Anticancer drugs such as Docetaxel, Paclitaxel, and Irinotecan are contraindicated with Voriconazole.

Antipsychotics such as Clozapine, Olanzapine, and Quetiapine are contraindicated with Voriconazole.

Antidepressants such as Sertraline, Escitalopram, and Venlafaxine are contraindicated with Voriconazole.

Antiepileptics such as Phenytoin, Carbamazepine, and Valproic Acid are contraindicated with Voriconazole.

Anticholinergics such as Atropine, Scopolamine, and Tropicamide are contraindicated with Voriconazole.

Antihistamines such as Lorazepam, Diphenhydramine, and Fexofenadine are contraindicated with Voriconazole.

Antidiarrheals such as Loperamide and Diphenoxylate are contraindicated with Voriconazole.

Antispasmodics such as Dicyclanil and Hyoscyamine are contraindicated with Voriconazole.

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The background risk of major birth defects and miscarriage for the indicated populations is unknown. In the background risk, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20% respectively.

Animal Data

Voriconazole was administered orally to pregnant rats during organogenesis (gestation days 6-17) at 10, 30, and 60 mg/kg. Voriconazole was associated with increased incidences of the malformations cleft palate and hydrocephalus at 10 mg/kg or greater, approximately 0.3 times the recommended human dose (RHD) based on body surface area comparisons, and cleft palate was observed at 30 mg/kg. [See **Warnings and Precautions (5.9)**.]

Reduced incidence of sacral and caudal vertebrae, skull, pelvic, and hind bone, supernumerary ribs, and extra-embryonic membranes were observed at 60 mg/kg. [See **Warnings and Precautions (5.9)**.]

Voriconazole was administered orally to pregnant rabbits during the period of organogenesis (gestation days 6-18) at 10, 30, and 60 mg/kg. Voriconazole was associated with increased incidences of the malformations cleft palate and hydrocephalus at 10 mg/kg or greater, approximately 0.3 times the recommended human dose (RHD) based on body surface area comparisons, and cleft palate was observed at 30 mg/kg. [See **Warnings and Precautions (5.9)**.]

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