

PATIENT INFORMATION

Voriconazole Tablets
(Vor-ih-CON-ah-zole)

for oral use

Read the Patient Information that comes with voriconazole tablets 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 are voriconazole tablets?

Voriconazole tablets are 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 tablets are safe and effective in children younger than 2 years old.

Do not take voriconazole tablets if you:

- **are allergic to voriconazole or any of the ingredients in voriconazole tablets.** See the end of this leaflet for a complete list of ingredients in voriconazole tablets.
- **are taking any of the following medicines:**
 - pimozide
 - rifampin
 - efavirenz
 - ergotamine, dihydroergotamine (ergot alkaloids)
 - tolvaptan
 - venetoclax
 - quinidine
 - carbamazepine
 - ritonavir
 - St. John’s Wort (herbal supplement)
 - lurasidone
 - sirolimus
 - long-acting barbitur phenobarbital
 - rifabutin
 - naloxegol
 - ivabradine

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.

Before you take voriconazole tablets, tell your healthcare provider about all of your medical conditions, including 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 tablets.
- have low potassium levels, low magnesium levels, and low calcium levels. Your healthcare provider may do blood tests before starting and during treatment with voriconazole tablets.
- have liver or kidney problems. Your healthcare provider may do blood tests to make sure you can take voriconazole tablets.
- have trouble digesting dairy products, lactose (milk sugar), or regular table sugar.

voriconazole tablets contain lactose.

- are pregnant or plan to become pregnant. voriconazole tablets 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 tablets. Talk to your healthcare provider about birth control methods that may be right for you.
- are breastfeeding or plan to breastfeed. 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 tablets.

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

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

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 tablets?

- **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 many voriconazole tablets, call your healthcare provider or go to the nearest hospital emergency room.

What should I avoid while taking voriconazole tablets?

- You should not drive at night while taking voriconazole tablets. Voriconazole tablets 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 tablets affect you.
- Avoid direct sunlight. Voriconazole tablets 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 tablets?

Voriconazole tablets 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
- **vision changes.** Symptoms of vision changes may include:
 - blurred vision
 - changes in the way you see colors
 - sensitivity to light or sun (photosensitivity). Voriconazole tablets can cause serious photosensitivity. There is an increased chance of skin toxicity while taking voriconazole tablets. This can happen with or without taking other medicines like methotrexate.
Photosensitivity reactions may also increase your risk of:
 - faster skin aging from the sun

- skin cancer

Call your healthcare provider right away if you get a new skin rash or your skin rash gets worse.

- **serious heart problems.** Voriconazole tablets 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 tablets 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 tablets. Your healthcare provider will decide if you can keep taking voriconazole tablets.
- **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
- **adrenal gland problems:**
 - Voriconazole tablets may cause reduced adrenal function (adrenal insufficiency).
 - Voriconazole tablets may cause overactive adrenal function (Cushing's syndrome) when voriconazole is used at the same time with corticosteroids.

Symptoms of adrenal insufficiency include:

- feeling tired
- lack of energy
- weakness
- nausea and vomiting
- feeling dizzy or lightheaded
- weight loss
- abdominal pain

Symptoms of Cushing's syndrome include:

- weight gain
- fatty hump between the shoulders (buffalo hump) and a rounded face (moon face)
- darkening of the skin on the stomach, thighs, breasts, arms
- thinning skin
- bruising easily
- high blood sugar
- excessive hair growth
- excessive sweating

- **bone problems.** Voriconazole tablets 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 tablets in adults include:

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

The most common side effects of voriconazole tablets in children include:

- o fever
- o diarrhea
- o low platelet counts
- o abnormal liver function tests
- o low blood calcium levels
- o low blood phosphate levels
- o vision changes
- o rash
- o stomach pain
- o high blood pressure
- o cough
- o low blood pressure
- o swelling in the arms and legs
- o high blood sugar levels
- o headache
- o fast heart beat (tachycardia)
- o nose bleeds
- o low blood potassium levels
- o inflammation of membranes
- o hallucinations (seeing or hearing things that are not there)
- o coughing up blood
- o constipation
- o low blood magnesium levels
- o fullness of the stomach area
- o vomiting
- o nausea
- o upper respiratory tract infection

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 tablets.

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 tablets?

- Store voriconazole tablets at room temperature, 59°F to 86°F (15°C 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 tablets, as well as all other medicines, out of the reach of children.

General information about the safe and effective use of voriconazole tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use voriconazole tablets for a condition for which it was not

prescribed. Do not give voriconazole tablets 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 tablets that is written for health professionals.

What are the ingredients of voriconazole tablets?

Active ingredient: voriconazole

Inactive ingredients:

croscarmellose sodium, lactose monohydrate, magnesium stearate, povidone, pregelatinized starch (corn), and a coating containing polyvinyl alcohol-part hydrolyzed, lactose monohydrate, titanium dioxide, macrogol/PEG and talc.

Distributed by: Solco Healthcare US, LLC
Somerset, NJ 08873, USA

Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd.
Xunqiao, Linhai, Zhejiang 317024, China

For more information about voriconazole tablets, call Solco Healthcare LLC. at 1-866-257-2597.

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

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