Voriconazole Cas No.: 137234-62-9

This medicine comes with a Patient Information Leaflet. Read it carefully. Ask your doctor, nurse, or pharmacist any questions that you may have about this medicine. Take this medication by mouth, at least 1 hour before or 1 hour after meals, usually every 12 hours or as directed by your doctor.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.

Voriconazole

CAS No.: 137234-62-9



Synonyms: (IUPAC) name

(2R,3S)-2-(2,4-difluorophenyl)-3- (5-fluoropyrimidin-4-yl)-1- (1H-1,2,4-triazol-1-yl) butan-2- ol

Identifiers

CAS number 137234-62-9 ATC code J02AC03 PubChem 71616 DrugBank APRD00543

Chemical data

Formula C16H14F3N5O Mol. mass 349.311 g/mol

Pharmacokinetic data

Bioavailability 96%

Protein binding 58%

Metabolism Hepatic cytochrome P450 enzymes CYP2C19, CYP2C9, CYP3A4

Half life Dose-dependent

Excretion

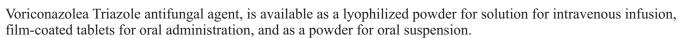
Therapeutic considerations

Pregnancy cat. D

Legal status

Prescription only

Routes IV, oral



Voriconazole is designated chemically as (2R,3S)-2-(2,4-difluorophenyl)-3-(5-fluoro-4- pyrimidinyl)-1-(1H-1,2,4-triazol-1-yl)-2-butanol with an empirical formula of C16H14F3N5O and a molecular weight of 349.3.

Voriconazole drug substance is a white to light-colored powder.

USES

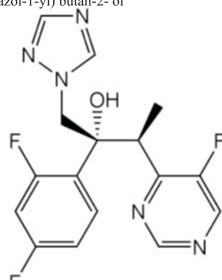
Voriconazole is an azole antifungal used to treat a variety of fungal infections.

HOW TO USE

This medicine comes with a Patient Information Leaflet. Read it carefully. Ask your doctor, nurse, or pharmacist any questions that you may have about this medicine.

Take this medication by mouth, at least 1 hour before or 1 hour after meals, usually every 12 hours or as directed by your doctor.

The dosage is based on your medical condition, response to therapy, and interacting drugs.





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Voriconazole

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This medication works best when the amount of medicine in your body is kept at a constant level. Therefore, take this drug at evenly spaced intervals.

Continue to take this medication until the full prescribed amount is finished. Stopping the medication too early may result in a return of the infection.

SIDE EFFECTS

Nausea/vomiting, diarrhea, and headache may occur. If any of these effects persist or worsen, notify your doctorserious side effects occur: vision changes (e.g., blurred vision, color vision changes), sensitivity of eyes to light (photophobia), bone/muscle/joint pain, weakness, mental/mood changes, muscle stiffness/spasm, restlessness, swelling of the ankles/feet, tiredness, easy bleeding/bruising, signs of infection (e.g., fever, persistent sore throat). Seek immediate medical attention if any of these rare but very serious side effects occur: fast/slow/irregular heartbeat, severe dizziness, fainting, change in the amount of urine, confusion, slurred speech, trouble breathing, chest/jaw/left arm pain, seizures. Voriconazole may rarely cause serious (possibly fatal) liver problems. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: yellowing eyes/skin, dark urine, persistent nausea/ vomiting, stomach/abdominal pain.

A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching, swelling, severe dizziness, trouble breathing.

Voriconazole can commonly cause a mild rash that is usually not serious. However, you may not be able to tell it apart from a rare rash that could be a sign of a severe allergic reaction. Therefore, seek immediate medical attention if you develop any rash.



Before taking voriconazole, tell your doctor or pharmacist if you are allergic to it; or to other azole antifungalsif you have any other allergies.

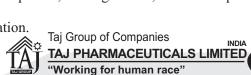
Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, recent chemotherapy, certain hereditary problems with digesting/absorbing the sugar galactose (e.g., galactose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption), untreated electrolyte imbalance (e.g., low potassium/magnesium/calcium levels), heart problems (e.g., irregular heartbeat, QT prolongation in the EKG, cardiomyopathy).

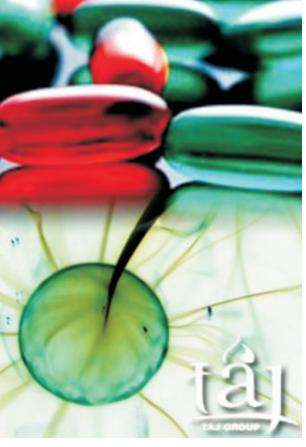
This drug may cause vision changes. Use caution while driving, using machinery, or doing any activity that requires clear vision. Do not drive at night.

Avoid alcoholic beverages since they can increase the risk of serious liver problems.

This medication may make you more sensitive to the sun. Avoid prolonged sun exposure, tanning booths, and sunlamps. Use a sunscreen and wear protective clothing when outdoors.

Before having surgery, tell your doctor or dentist that you are using this medication.









MISSED DOSE

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children

DOSAGE

Voriconazole comes as a tablet and a suspension to take by mouth. It is usually taken every 12 hours on an empty stomach, at least 1 hour before or 1 hour after a meal. To help you remember to take voriconazole, take it at around the same times every day.

Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take voriconazole exactly as directed

If you are taking voriconazole suspension, shake the closed bottle for about 10 seconds before each use to mix the medication evenly.

Do not mix the suspension with any other medications, water, or any other liquid. Always use the measuring device that comes with your medication. You may not get the right amount of medication if you use a household spoon to measure your dose.

At the beginning of your treatment, you may receive voriconazole by intravenous (into a vein) injection. When you begin taking voriconazole by mouth, your doctor may start you on a low dose and increase your dose if your condition does not improve. Your doctor also may decrease your dose if you experience side effects from voriconazole.

The length of your treatment depends on your general health, the type of infection you have, and how well you respond to the medication. If you are taking voriconazole for esophageal candidiasis, you will take it for at least 14 days. If you are taking voriconazole for aspergillosis, you may take it for several months or longer. Continue to take voriconazole even if you feel well.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

Information: The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers, also that the information on the PTCL Safety web site, where this page was hosted, has been copied onto many other sites, often without permission. If you have any doubts about the veracity of the information that you are viewing, or have any queries, please check the URL that your web browser displays for this page. If the URL begins "www.tajapi.com/www/Denatonium Benzoate.htm/" the page is maintained by the Safety Officer in Physical Chemistry at Oxford University. If not, this page is a copy made by some other person and we have no responsibility for it.

The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

http://www.tajapi.com

or by contacting the sponsor, Taj Pharmaceuticals Limited., at: 91 022 30601000.

This leaflet was prepared by

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