

Vorier

Voriconazole USP Tablet

Composition

Vorier 200 mg Tablet: Each film coated tablet contains Voriconazole USP 200 mg.

Pharmacology

Voriconazole is a triazole antifungal agent. Its primary mode of action is the inhibition of fungal cytochrome P-450-mediated 14 α -lanosterol demethylation, an essential step in ergosterol biosynthesis. Voriconazole is more selective than some other azole drugs for fungus as opposed to various mammalian cytochrome P-450 enzyme systems. The subsequent loss of normal sterols correlates with the accumulation of 14 α -methyl sterols in fungi and may be responsible for its fungistatic/fungicidal activity.

Indication

Adults and pediatric patients (2 years of age and older) for the treatment of following fungal infections:

- Invasive aspergillosis
- Candidemia in non-neutropenics and other deep tissue Candida infections
- Esophageal candidiasis
- Serious fungal infections caused by *Scedosporium apiospermum* and *Fusarium* species including *Fusarium solani*, in patients intolerant or refractory to other therapy

Dose and Administration

a) *Route of Administration: Oral*

Dose: Voriconazole Tablet is to be taken at least one hour before or one hour following a meal.

For Patients 40 kg or above: Loading Dose: 400 mg twice daily (for the first 24 hours)

Maintenance Dose: 200 mg twice daily (from the 2nd day)

For Patients less than 40 kg: Loading Dose: 200 mg twice daily (for the first 24 hours)

Maintenance Dose: 100 mg or 150 mg twice daily (from the 2nd day)

Dose Adjustment:

If patient (adult) response is inadequate, the oral maintenance dose may be increased from 200 mg to 300 mg every 12 hours. For adult patients weighing less than 40 kg, the oral maintenance dose may be increased from 100 mg to 150 mg every 12 hours. If patients are unable to tolerate 300 mg orally every 12 hours, reduce the oral maintenance dose by 50 mg steps to a minimum of 200 mg every 12 hours (or to 100 mg every 12 hours for adult patients weighing less than 40 kg).

Treatment duration depends upon patients' clinical and mycological response.

Contra-indication

- Hypersensitivity to Voriconazole.
- Co-administration with astemizole, cisapride, pimozone or quinidine, sirolimus due to of serious adverse reactions.
- Co-administration with rifampin, carbamazepine, long-acting barbiturates, efavirenz, rifabutin, ergot alkaloids, St. John's wort due to risk of loss of efficacy.

Warning and Precaution

Long-term treatment, long-term exposure (treatment or prophylaxis) greater than 180 days (6 months) requires careful assessment of the benefit-risk balance and physicians should therefore consider the need to limit the exposure to voriconazole.

Side-effect

Common: The most frequently reported adverse events in the therapeutic trials were visual disturbances, fever, rash, vomiting, nausea, diarrhea, headache, sepsis, peripheral edema, abdominal pain and respiratory disorder. The treatment-related adverse events which most often led to discontinuation of Voriconazole therapy were elevated liver function tests, rash and visual disturbances.

Rare: Agitation, irritability, increased sensitivity of the skin to sunlight etc.

Pregnancy & Lactation

Voriconazole can cause fetal harm when administered to pregnant women. Inform pregnant women of risk to the fetus.

Use in children & adolescents

Safety and effectiveness in pediatric patients below the age of 2 years has not been established. Therefore, Voriconazole is not recommended for pediatric patients less than 2 years of age.

Drug interaction

a) *With medicine:* Voriconazole is metabolized by the human hepatic cytochrome P450 enzymes CYP2C19, CYP2C9 and CYP3A4. Results of in vitro metabolism studies indicate that the affinity of Voriconazole is highest for CYP2C19, followed by CYP2C9 and is appreciably lower for CYP3A4. Inhibitors or inducers of these three enzymes may increase or decrease the plasma concentration of Voriconazole respectively.

b) *With food & others:* Food may decrease the oral absorption of voriconazole; therefore, oral formulations of voriconazole should be taken 1 hour before or 1 hour after meals.

Overdose

In an overdose, haemodialysis may assist in the removal of Voriconazole and SBECD from the body.

Storage

Store below 30°C. protect from light and moisture. Keep all medicines out of reach of children.

Packing

Vorier 200 mg Tablet: Each box contains 10 (1x10's) Tablets in Blister Pack.



Manufactured by

ONE PHARMA LTD.

C-23-24, BSCIC I/A

Bogura, Bangladesh

LF0089

VOR Rev.01