Vorizol

Tablet & Suspension

DRUG INTERNATIONAL LTD.

Composition : **Vorizol-50 :** Each film coated tablet contains Voriconazole USP 50 mg.

Vorizol-200 : Each film coated tablet contains Voriconazole USP 200 mg.

Vorizol Suspension : Each 5ml reconstituted suspension contains Voriconazole USP 200 mg.

Pharmacology : Voriconazole is an antifungal drug. The oral bioavailability of voriconazole is estimated to be 96%. Plasma protein binding is estimated to be 58%. Voriconazole is metabolized by the human hepatic cytochrome P450 enzymes, CYP2C19, CYP2C9 and CYP3A4. Voriconazole is eliminated via hepatic metabolism with less than 2% of the dose excreted unchanged in the urine.

Indications : Vorizol is an azole antifungle medicine . It is indicated for use in patients 12 years of age and older in the treatment of following fungal infections. * Invasive aspergillosis * Candidemia (nonneutropenics) and disseminated candidiasis in skin, abdomen, kidney, bladder wall and wounds. * Esophageal candidiasis * Serious infections caused by Scedosporium apiospermum and Fusarium Species including Fusarium solani, in patients intolerant of, or refractory to, other therapy.

Dosage and Administration : Vorizol tablet and powder for suspension are to be taken atleast one hour before or one hour following a meal.

* At or over 40 kg body weight is loading dose regimen is 400 mg or 10 ml every 12 hours (for the first 24 hours) and maintenance dose (after first 24 hours) is 200 mg or 5 ml twice daily.

* Below 40 kg body weight is loading dose regimen is 200 mg or 5 ml every 12 hours (for the first 24 hours) and maintenance dose (after first 24 hours) is 100 mg or 2.5 ml twice daily. Or, as directed by the registered physician. Reconstitution Instructions : Shake the bottle well before adding water to loosen the powder. Add 25 ml of boiled and cooled water to the bottle (5 spoon of provided spoon). Shake the closed bottle vigorously until powder mixed completely with the water. Store reconstituted suspension between 15°- 30°C. Discard suspension 14 days after reconstitution.

Contraindication : It is contraindicated in patients with known hypersensitivity to voriconazole or any other components of this drug.

Precaution : It should be given with caution in patients with hepatic and renal impairment patients.

Side effects : The most common side effects are abdominal pain, anaemia, blurred vision, headache, chest pain, nausea, diarrhea.

Use in pregnancy and lactation : There are no adequate and well-controlled studies in pregnant woman. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether it is excreted in human milk. So a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Use in Child : There is no data available.

Drug Interactions : Voriconazole interacts with the following drugs: terfendine, astemizole, cisapride, pimozide or quindine.

Overdose : There is no date avialable.

Storage : Store Vorizol tablet below 30°C in a dry place, away from light. Store powder for suspension between 2°- 8° C temperature. Keep out of the reach of children.

Packing : **Vorizol-50 :** Each box contains 1 x 10's tablets in blister pack.

Vorizol-200 : Each box contains 1 x 7's tablets in blister pack.

Vorizol Suspension : Each bottle contains dry powder for the preperation of 40 ml suspension.