Zolvo®

Voriconazole

COMPOSITION:
Zolvo ® 50 Tablet: Each film coated tablet contains Voriconazole USP 50 mg.
Zolvo ® 200 Tablet: Each film coated tablet contains Voriconazole USP 200 mg.
Zolvo ® PFS: Each 1 ml suspension contains Voriconazole USP 40 mg.

PHARMACOLOGY:
Voriconazole is a triazole antifungal medication used to treat serious fungal infections. Voriconazole binds & inhibits ergosterol synthesis by inhibiting cytochrome P-450-dependent 14α-sterol demethylase. The inhibition of 14α-sterol demethylase results in a depletion of ergosterol in fungal cell membrane. Voriconazole is more selective than some other azole drugs for fungus as opposed to various mammalian cytochrome P-450 enzyme systems.

INDICATION:
Zolvo ® is an azole antifungal indicated for use in adults and pediatric patients (2 years of age and older) for the treatment of-
- 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.

DOSE & ADMINISTRATION:
Zolvo ® Tablet and Powder for Suspension are to be taken at least one hour before or one hour after a meal.
• At or over 40 kg body weight: 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: 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.
Dosage 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 or its excipients.
- Co-administration with terfenadine, astemizole, cisapride, pimozide or quinidine, sirolimus due to risk of serious adverse reactions.
- Co-administration with rifampicin, carbamazepine, long-acting barbiturates, efavirenz, ritonavir, rifabutin, ergot alkaloids, due to risk of loss of efficacy.
- Hepatic impairment: Use half the maintenance dose in patients with mild to moderate hepatic impairment.

WARNING AND PRECAUTION:
Long -term treatment:
Long term exposure (treatment or prophylaxis) greater than 180 days (6 month) requires careful assessment of the benefit-risk balance and physicians should therefore consider the need to limit the exposure to Voriconazole.

SIDE EFFECTS:
Most common adverse reactions : visual disturbances, fever, nausea, rash, vomiting, chills, headache, liver function test abnormal, tachycardia, hallucinations.

USE IN PREGNANCY & LACTATION:
There are no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

USE IN CHILDREN & ADOLESCENTS:
Safety and efectiveness 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:
- CYP3A4, CYP2C9 and CYP2C10 inhibitors and inducers: Adjust Voriconazole dosage and monitor for adverse reactions or lack of efficacy.
- Voriconazole may increase the concentrations and activity of drugs that are CYP3A4, CYP2C9 and CYP2C19 substrates. Reduce dosage of these other drugs and monitor for adverse reactions.
- Phenytoin or Efavirenz: with co-administration, increase maintenance oral and intravenous dosage of Voriconazole.

OVERDOSE:
There is no data found about overdose of Voriconazole.

STORAGE:
Store in a dry and cool place below 30°C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:
Zolvo ® 50 Tablet: Each box contains 1x10's tablets in Alu-PVC blister pack.
Zolvo ® 200 Tablet: Each box contains 1x10's tablets in Alu-PVC blister pack.
Zolvo ® PFS: Each bottle contains powder for suspension for the preperation of 40 ml suspension with a measuring spoon.

Manufactured by
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