Voricon

Voriconazole Tablet/ Powder for Suspension

Presentation

Voricon 50: Each film coated tablet contains Voriconazole USP 50 mg.

Voricon 200: Each film coated tablet contains Voriconazole USP 200 mg.

Voricon PFS: Each 1ml suspension contains Voriconazole USP 40 mg.

Indications

Voricon is an azole antifungal indicated for use in 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

Reconstitution Instructions

Shake the botle 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 below 30°C.

Discard suspension 14 days after reconstitution.

Dosage and Administration

Voricon tablet and powder for oral suspension are to be taken at least 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.

Side effects

Most common adverse reactions (incidence ≥ 2%): visual disturbances, fever, nausea, rash, vomiting, chills, headache, liver function test abnormal, tachycardia, hallucinations.

Contraindications

- 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 rifampin, carbamazepine, long-acting barbiturates, efavirenz, ritonavir, rifabutin, ergot alkaloids, and St. John's Wort due to risk of loss of efficacy.

Drug Interactions

- CYP3A4, CYP2C9, and CYP2C19 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.

Use in Specific Populations

- Pregnancy: Voriconazole can cause fetal harm when administered to pregnant woman. Inform pregnant women of risk to the fetus.
- Pediatrics: Safety/effectiveness in patients <12 years has not been established.
- Hepatic impairment: Use half the maintenance dose in patients with mild to moderate hepatic impairment (Child-Pugh Class A and B).

Storage Conditions

Store in a cool and dry place, away from light. Powder for Suspension store between 2-8° C temperature. Keep out of the reach of children.

Commercial Pack

Voricon 50: Each box contains 2 blister packs of 4 tablets.

Voricon 200: Each box contains 2 blister packs of 4 tablets.

Voricon PFS: Each box contains 1 bottle of 40 ml powder for suspension.

Manufactured by:
general GENERAL
Pharmaceuticals Ltd.
Kaliakair, Gazipur, Bangladesh

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