VHOPE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **VHOPE** [voriconazole 200mg tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Voriconazole is a triazole antifungal agent. Voriconazole exent its effect primarily by inhibiting the fungal cytochrome P450CYP3A enzyme lanosterol 14-α- demethylase, preventing the conversion of lanosterol to ergosterol.

INDICATION: Indicated for the treatment of invasive aspergillosis, fluconazole resistant serious invasive *candida* infections (including *C. krusei*), esophageal candiasis, serious fungal infection caused by *scedosporium spp.* and *fusarium spp.* including *fusarium solani*. in patients intolerant of or refractory to other therapy. **DOSAGE AND ADMINISTRATION:** If patient is unable to tolerate treatment at a higher dose, reduce the oral dose by 50 mg steps to the 200 mg twice daily (or 100 mg twice daily for patients less than 40 kg) maintenance dose. In case of use as prophylaxis, Children (2 to <12 years) and young adolescents with low body weight (12 to 14 years and <50 kg) Voriconazole should be dosed as children as these young adolescents may metabolize voriconazole more similarly to children than to adults. **CONTRAINDICATION: C**ontraindicated in patients with known hypersensitivity to Voriconazole or its excipients, co-administration of the CYP3A4 substrates, terfenadine, astemizole, cisapride, pimozide or quinidine, rifampicin, rifabutin, carbamazepine, phenobarbital, ritonavir, ergot alkaloids, sirolimus and efavirenz. **WARNINGS & PRECAUTIONS**: Use cautiously or stop the voriconazole in patient with visual disturbances, hepatic toxicity, pregnancy (category D), arrhythmias and QT prolongation, hypokalemia, hypomagnesemia, hypocalcemia, renal impairment, dermatological reactions, skeletal adverse events. Monitoring of hepatic function, pancreatic function and cardiovascular effects are required. **DRUG INTERACTIONS**: Rifampin, rifabutin, efavirenz, ritonavir, carbamazepine, long acting barbiturates, phenytoin, st. john's wort, oral contraceptives, fluconazole, other HIV protease inhibitors, other NNRTIs, sirolimus, tacrolimus, everolimus, terfenadine, astemizole, cisapride, pimozide, quinidine, ergot alkaloids, cyclosporine, methadone, fentanyl, alfentanil, oxycodone, NSAIDs, warfarin, omeprazole, benzodiazepines, HMG-coA reductase inhibitors, dihydropyridine calcium channel blockers, sulfonylurea oral hypoglycemic and vinca alkaloids. **ADVERSE REACTIONS**: Gastroenteritis, influenza-like illness, pancytopenia, bone marrow depression, leukopenia, thrombocytopenia, anaemia (macrocytic, megaloblastic, microcytic, normocytic), purpura, sinusitis, hypoglycaemia, hypokalaemia, bilirubinemia, depression, hallucination, anxiety, headache, dizziness, confusional state, tremor, agitation, paraesthesia, visual disturbances (including blurred vision, chromatopsia, photophobia), colour perception, altered/enhanced visual perception, colour vision change, oedema peripheral, thrombophlebitis, hypotension, phlebitis, acute respiratory distress syndrome, pulmonary oedema, respiratory distress, chest pain, jaundice, cholestatic jaundice, transaminase abnormality, rash, exfoliative dermatitis, face oedema, photosensitivity reaction, maculo-papular rash, macular rash, papular rash, cheilitis, pruritus, alopecia, erythema, renal failure acute, haematuria, kidney function abnormal, pyrexia, fever, headache, elevated liver function tests (including ASAT, ALAT, alkaline phosphatase, GGT, LDH, bilirubin), blood creatinine increased and hepatic enzyme increased.

MARKETED BY:

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(Additional information is available on request)