Vcand
Voriconazole

COMPOSITION

Vcand 50 mg Tablet: Each film coated tablet contains Voriconazole USP 50 mg.
Vcand 200 mg Tablet: Each film coated tablet contains Voriconazole USP 200 mg.
Vcand 40 ml PFS: Each ml (reconstituted) suspension contains Voriconazole USP 40 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

Voriconazole is indicated in 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 of, or Refractory to, other therapy

Dosage and Administration :

Voriconazole tablet and powder for 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. Or, as directed by the registered physician.

Reconstitution Instructions :

Shake the bottle well before adding water to loosen the powder. Add 30 ml of boiled and cooled water to the bottle. Shake the closed bottle vigorously until powder mixed completely with the water. Store reconstituted suspension between 15^{O}- 30^{O}C.
Discard suspension 14 days after reconstitution.

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.

CONTRAINDICATION

In patients with known hypersensitivity to Voriconazole or to any of the excipients. Coadministration of CYP3A4 substrates, Terfenadine, Astem- izole, Cisapride, Pimozide or Quinidine, Sirolimus, Rifampin, Carbamazepine and long-acting barbiturates, high-dose Ritonavir (400 mg Q12h), Rifabutin, Ergot alkaloids, St. John's Wort with Voriconazole is also contraindicated.

SIDE EFFECT

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.

DRUG INTERACTION

Voriconazole is metabolized by the human hepatic cytochrome P450 enzymes CYP2C19, CYP2C9, and CYP3A4. Results of in vitro metabolism studies indicate that the afinity of Voriconazole is highest for CYP2C19, followed by CYP2C9, and is apprecia-

bly lower for CYP3A4. Inhibitors or inducers of these three enzymes may increase or decrease the plasma concentration of Voriconazole respectively.

PREGNANCY & LACTATION
Voriconazole can cause fetal harm when administered to a pregnant woman.

It is not known whether Voriconazole is excreted in the milk of laboratory animals or in human breast milk. Voriconazole must not be used in nursing mothers unless the benefit clearly outweighs the risk.

PEDIATRIC USE
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.

GERIATRIC USE
No dose adjustment is necessary for geriatric patients.

STORAGE CONDITION
Store below 30^{O}C, protect from light & moisture. Keep all medicines out of the reach of children.

COMMERCIAL PACK
Vcand 50 mg Tablet: Each pack contains 2X10's tablets in alu-alu blister pack.
Vcand 200 mg Tablet: Each pack contains 2X6's tablets in alu-alu blister pack.
Vcand 40 ml PFS: Each amber color glass bottle containing dry powder to reconstitute 40 ml suspension.

Manufactured by
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L I M I T E D
A-116, BSCIC, Industrial Estate
TONGI, GAZIPUR, BANGLADESH

For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.