Zolivox™

Linezolid USP

Composition
Zolivox™ 400 Tablet: Each tablet contains Linezolid USP 400 mg
Zolivox™ 600 Tablet: Each Tablet contains Linezolid USP 600 mg

Pharmacology
Linezolid is an antibiotic in the oxazolidinone class. Linezolid is bacteriostatic with a unique mechanism of action. It inhibits protein synthesis by binding to a site on the bacterial 23S ribosomal RNA of the 50S subunit.

Indication
Zolivox™ is an oxazolidinone-class antibacterial indicated in adults and children for the treatment of the following infections caused by susceptible Gram-positive bacteria:
Nosocomial pneumonia; Community-acquired pneumonia; complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis; uncomplicated skin and skin structure infections Vancomycin-resistant Enterococcus faecium infections.

Dosage and Administration

	Dosage, Route, and Frequency of Administration		
Infection	**Pediatric Patients**	**Adults and Adolescents**	**Duration (days)**
Nosocomial pneumonia	10 mg/kg intravenous or oral every 8 hours	600 mg intravenous or oral every 12 hours	10 to 14
Community-acquired pneumonia, including concurrent bacteremia			
Complicated skin and skin structure infections			
Vancomycin-resistant *Enterococcus faecium* infections, including concurrent bacteremia	10 mg/kg intravenous or oral every 8 hours	600 mg intravenous or oral every 12 hours	14 to 28
Uncomplicated skin and skin structure infections	< 5 yrs: 10 mg/kg oral every 8 hours 5-11 yrs: 10 mg/kg oral every 12 hours	Adults: 400 mg oral every 12 hours Adolescents: 600 mg oral every 12 hours	10 to 14

Drug Interaction
Monoamine oxidase inhibitors and potential for interaction with adrenergic and serotonergic agents

Contraindications
Known hypersensitivity to linezolid or any of the other product components. Patients taking any MAOI or within two weeks of taking an MAOI.

Use in Pregnancy and Lactation
Pregnancy category C: There are no adequate and well controlled studies in pregnant women. Linezolid should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Linezolid and its metabolites are excreted in the milk of lactating rats. Concentrations in milk were similar to those in maternal plasma. It is not known whether linezolid is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Nezolid is administered to a nursing woman.

Overdose
In the event of overdosage, supportive care is advised, with maintenance of glomerular filtration. Hemodialysis may facilitate more rapid elimination of linezolid. In a Phase 1 clinical trial, approximately 30% of a dose of linezolid was removed during a 3-hour hemodialysis session beginning 3 hours after the dose of linezolid was administered. Data are not available for removal of linezolid with peritoneal dialysis or hemoperfusion. Clinical signs of acute toxicity in animals were decreased activity and ataxia in rats and vomiting and tremors in dogs treated with 3000 mg/kg/day and 2000 mg/kg/day, respectively.

Storage
Keep out of the reach of children. Keep in a cool & dry place. Store below 30° C. Protect from light.

How supplied
Zolivox™ 400 Tab: Each box contains 1X10's tablet in alu-alu blister pack
Zolivox™ 600 Tab: Each box contains 1X10's tablet in alu-alu blister pack

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH