ZOLINE

LINEZOLID USP

Compositions:
Zoline 400 Tablet: Each film coated tablet contains Linezolid INN 400 mg. Zoline 600 Tablet: Each film coated tablet contains Linezolid INN 600 mg. Zoline 600 IV Infusion: Each 300 ml solution contains Linezolid INN 600 mg.

Pharmacology:
Linezolid is a synthetic, antibacterial agent belonging to a new class of antibiotics, the oxazolidinones, with in vitro activity against Gram positive aerobic bacteria, some Gram positive anaerobic bacteria and certain Gram negative bacteria. It selectively inhibits bacterial protein synthesis via a mechanism of action different from that of other antibacterial agents. Linezolid binds to the 23S ribosomal RNA of the 50S subunit of the bacterial ribosome and prevents the formation of a functional 70S initiation complex which is an essential component of the bacterial translation process. The results of time-kill studies have shown Linezolid to be bacteriostatic against enterococci and staphylococci. For streptococci, Linezolid was found to be bactericidal for the majority of strains.

Dosage And Administration:
Nosocomial pneumonia, Community-acquired pneumonia including concurrent bacteremia and Complicated skin and skin structure infections: 10 mg/kg intravenously or orally every 8 hours for pediatric patients (Birth through 11 Years of Age) and 600 mg intravenously or orally every 12 hours for adults and adolescents for 10 to 14 days. Vancomycin-resistant Enterococcus faecium infections, including concurrent bacteremia: 10 mg/kg intravenously or orally every 8 hours for pediatric patients (Birth through 11 Years of Age) and 600 mg intravenously or orally every 12 hours for adults and adolescents for 14 to 28 days. Uncomplicated skin and skin structure infections:

Contraindications:
Zoline formulations are contraindicated for use in patients who have known hypersensitivity to Linezolid or any of the other product components.

Warning And Precaution:
Patients who develop recurrent nausea or vomiting, unexplained acidosis, or low bicarbonate level while receiving Linezolid should receive immediate medical evaluation. Where administration of Linezolid and concomitant serotonergic agents is clinically appropriate, patients should be closely observed for signs and symptoms of serotonin syndrome such as cognitive dysfunction, hyperpyrexia, hyper reflexia and incoordination. If signs or symptoms occur physicians should consider discontinuation of either one or both agents. If the concomitant serotonergic agent is withdrawn, discontinuation symptoms can be observed. If patients experience symptoms of visual impairment, such as changes in visual acuity, changes in color vision, blurred vision, or visual field defect, prompt ophthalmic evaluation is recommended. Convulsions have been reported in patients when treated with Linezolid. In some of these cases, a history of seizures or risk factors for seizures was reported.

Side Effects:
Most of the adverse events reported with Linezolid were mild to moderate in intensity. The most common adverse events in patients treated with Linezolid were diarrhea, headache and nausea. Other adverse included oral moniliasis, vaginal moniliasis, hypertension, dyspepsia, localized abdominal pain, pruritus, and tongue discoloration.

Use in Pregnancy and Lactation:
Pregnancy: 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. Lactation: It is not known whether Linezolid is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Linezolid is administered to a nursing woman.

Drug Interaction:
Monoamine Oxidase Inhibition: Linezolid is a reversible, nonselective inhibitor of monoamine oxidase. Therefore, Linezolid has the potential for interaction with adrenergic and serotonergic agents. Adrenergic Agents: Some individuals receiving Linezolid may experience a reversible enhancement of the pressor response to indirect-acting sympathomimetic agents, vasopressor or dopaminergic agents. Initial doses of adrenergic agents, such as dopamine or epinephrine, should be reduced and titrated to achieve the desired response. Serotonergic Agents: Physicians should be alert to the possible signs and symptoms of serotonergic syndrome in patients receiving concomitant Linezolid and serotonergic agents.

Overdosage:
No cases of overdose have been reported. Symptomatic and supportive care is advised together with maintenance of glomerular filtration. Approximately 30% of a Linezolid dose is removed during 3 hours of haemodialysis. No data are available for the removal of Linezolid by peritoneal dialysis or haemoperfusion.

Storage:
Linezolid formulations should be stored at room temperature 25 °C, away from light and moisture. All medicines should be kept away from children.

Packing:
Zoline 400 Tablet: Each box contains 1 x 10 tablets in a blister strip. Zoline 600 Tablet: Each box contains 1 x 10 tablets in a blister strip. Zoline 600 IV Infusion: Each box contains 1 bottle of 300 ml solution for IV infusion, one infusion set, butterfly needle, alcohol pad & a hanging net.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.