ESOLOK

ESOMEPRAZOLE

Compositions:
Esolok 20 capsule: Each capsule contains enteric coated pellets of esomeprazolemagnesium trihydrate USP equivalent to esomeprazole 20 mg. Esolok 40 capsule: Each capsule contains enteric coated pellets of Esomeprazole magnesium trihydrate USP equivalent to esomeprazole 40 mg. Esolok 20 tablet: Each enteric coated tablet contains esomeprazole magnesium trihydrate BP equivalent to esomeprazole 20 mg. Esolok 40 tablet: Each enteric coated tablet contains esomeprazole magnesium trihydrate BP equivalent to esomeprazole 40 mg. Esolok IV injection: Each vial contains sterile Esomeprazole Sodium BP equivalent to 40 mg Esomeprazole.

Pharmacology:
Esolok is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H+/K+ -ATPase in the gastric parietal cell.By acting specifically on the proton pump, Esolok blocks the final step in acid production. thus reducing gastric acidity.

Dosage And Administration:
Healing of Erosive Esophagitis: 20mg or 40mg Once daily for 4 to 8 weeks, Maintenance of healing of Erosive Esophagitis: 20mg Once daily,Symptomatic Gastroesophageal Reflux Disease: 20mg Once daily for 4 weeks,Risk reduction of NSAID induced Gastric Ulcer: 20mg or 40mg Once daily for up to 6 month. Eradication of Helicobacter pylori in combination with Amoxicillin and Clarithromycin. Esolok (40 mg,Once daily)Amoxicillin-(1000 mg,Once daily),Clarithromycin (1000 mg,Once daily) for 10 days.

Contraindications:
Esomeprazole is contraindicated in those patients who have known hypersensitivity to any component of the formulation.

Warning And Precaution:
Exclude the possibility of malignancy when gastric ulcer is suspected and before treatment for dyspepsia. When using in combination with antibiotic refer to the prescribing information of the respective antibiotics. For patient with severe liver impairment, a dose of 20 mg of esomeprazole should not be exceeded.

Side Effects:
Headache. abdominal pain, diarrhoea, flatulence, nausea or vomiting etc.

Use in Pregnancy and Lactation:
Use in Pregnancy:There are no adequate and well-controlled studies with esomeprazole in pregnant women. This drug may be used during pregnancy (as it is Pregnancy Category B) only if clearly needed. Use in Lactation:The excretion of esomeprazole in human breast milk has not been studied. As esomeprazole is likely to be excreted in human breast milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Drug Interaction:
Esomeprazole potentially can increase the concentration of diazepam in blood by decreasing the elimination of diazepam in the liver. The absorption of certain drugs may be affected by stomach acidity. Therefore. esomeprazole and other PPls that reduce stomach acid also reduce the absorption and concentration of ketoconazole and increase the absorption and concentration of digoxin In blood. This may lead to reduced effectiveness of ketoconazole or

increased digoxin toxicity respectively.

Overdosage:
A single oral dose of Esomeprazole at 510 mg/kg (about 103 times the human dose on a body surface area basis), has been lethal to rats. The major signs of acute toxicity are reduced motor activity, changes in respiratory frequency, tremor, ataxia, and intermittent clonic convulsions. There have been no reports of overdose with Esomeprazole. No specific antidote for Esomeprazole is known. Since Esomeprazole is extensively protein bound, it is not expected to be removed by dialysis. In the event of overdosage, treatment should be symptomatic and supportive. As with the management of any overdose, the possibility of multiple drug ingestion should be considered.

Storage:
Store in a cool (15- 30°C) and dry place protected from light and moisture. Keep out of the reach of children

Packing:
Esolok 20 capsule : Each box contains 10x10's capsule in Alu-Alu blister pack. Esolok 40 capsule : Each box contains 10x10's capsule in Alu-Alu blister pack. Esolok 20 tablet : Each box contains 10x10's tablet in Alu-Alu blister pack. Esolok 40 tablet : Each box contains 3x10's tablet in Alu-Alu blister pack. Esolok IV injection: Each combipack contains 1 vial of 40 mg Esomeprazole and 1 ampoule of 5 ml 0.9% Sodium Chloride Injection.

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