ESOLOK MUPS

ESOMEPRAZOLE

Compositions:
Esolok MUPS 20 Tablet: Each MUPS (Multiple Unit Pellet System) tablet contains Esomeprazole Magnesium Trihydrate USP as enteric coated pellets equivalent to Esomeprazole 20 mg. Esolok MUPS 40 Tablet: Each MUPS (Multiple Unit Pellet System) tablet contains esomeprazole Magnesium Trihydrate USP as enteric coated pellets equivalent to esomeprazole 40 mg. MUPS: Multiple Unit Pellet System is known as MUPS. The tablets are prepared by compaction of modified release coated pellets along with cushioning granules. MUPS is the latest technology which combines both tablets and pellets – filled capsule in one single dosage form.

Pharmacology:
Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H+/K+ -ATPase in the gastric parietal cell. It blocks the final step in acid production thus reducing gastric acidity. Clinical Advantage of Esolok MUPS Tablet: Ensures greater bioavailability 2. Ensures Tmax & Cmax very fast 3.Once daily dose 4. No fluctuation in plasma concentration of drug 5. Ensures reduction of esophageal residence time 6. Ensure less possibility of dose dumping 7. Ensures less chance of localized irritation 8. Gives efficacy very fast & effective for long time. Pharmacodynamic Advantage: Pellets of MUPS tablet quickly transfer from stomach to intestine as a result absorption occur very fast. Due to small size pellets it covers largest area and maximum absorption occurs in intestine

Dosage And Administration:
For Adults from age 18 years- Indication Dosage Frequency Gastro Esophageal Reflux Disease (GERD) Erosive Esophagitis 40 mg Once daily for 4 to 8 weeks Maintenance of healing of Erosive Esophagitis 20 mg Once daily Symptomatic Gastroesophageal Reflux Disease 20 mg Once daily for 4 weeks Risk reduction of NSAID induced Gastric Ulcer 20 mg/40 mg Once daily for up to 6 months Helicobacter pylori Eradication (Esomeprazole MUPS tablet with Amoxicillin & Clarithromycin) 40 mg Twice daily for 7 days   Adolescents aged 12 – 17 years- Indication Dosage Frequency Gastro Esophageal Reflux Disease (GERD) Erosive Esophagitis 40 mg Once daily for 4 weeks Maintenance of healing of Erosive Esophagitis 20 mg Once daily Helicobacter pylori Eradication (Esomeprazole MUPS tablet with Amoxicillin & Clarithromycin) 20 mg Twice daily for 7 days *Esomeprazole MUPS Tablet is not recommended for children under 12 years of age Method of Taking Tablet: Shallow the whole tablet with a glass of water. The tablet should not be chewed or crushed.   If patients have complications to swallow the tablet, put the tablet into a glass of water then stir the preparation until the tablet disintegrate and drink liquid within 30 minutes. Stir the mixture just always before drinking.   &

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, diarrhea, flatulence, nausea or vomiting etc.

Use in Pregnancy and Lactation:
Manufacturer advices caution and there is no information available. It is not known whether Esomeprazole is excreted in breast milk or not.

Drug Interaction:
Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability such as Ketoconazole, Iron Salts and Digoxin.

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 (below 30° C) and dry place, protect from light. Keep out of reach of children.

Packing:
Esolok MUPS 20 Tablet: Each box contains 5x10 MUPS tablets in Alu-Alu blister pack.
Esolok MUPS 40 Tablet: Each box contains 3x10 MUPS tablets in Alu-Alu blister pack.

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