Ema

Esomeprazole BP

Presentation

Ema-20 Tablet: Each enteric-coated tablet contains Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg.

Ema-40 Tablet: Each enteric-coated tablet contains Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 40 mg.

Ema-20 Capsule: Each capsule contains Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg as enteric-coated pellets.

Ema-40 Capsule: Each capsule contains Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 40 mg as enteric-coated pellets.

Ema-40 IV Injection: Each vial contains sterile powder of Esomeprazole Sodium BP equivalent to Esomeprazole 40 mg and each ampoule contains 5 ml of 0.9% Sodium Chloride Injection BP.

Description

Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H^+/K^+-ATPase in the gastric parietal cell. Esomeprazole is the S-isomer of omeprazole. Esomeprazole is completely metabolized by the cytochrome P450 system. Its protein binding is 97% and half life is 1-1.5 hours.

Indication

Short-term (4-8 weeks) treatment of erosive esophagitis, maintaining symptom resolution and healing of erosive esophagitis, treatment of symptomatic gastroesophageal reflux disease, as part of a multidrug regimen for *Helicobacter pylori* eradication in patients with peptic ulcer, Zollinger-Ellison Syndrome, prevention of gastric ulcers associated with continuous NSAID therapy.

Dosage and administration

Tablet:

Adult

Indication	Dose	Frequency
Gastroesophageal reflux disease (GERD)		
Healing of erosive esophagitis	20 mg or 40 mg	Once daily for 4 to 8 weeks*
Maintenance of healing of erosive esophagitis	20 mg	Once daily**
Symptomatic GERD	20 mg	Once daily for 4 weeks***
Risk reduction of NSAID-associated gastric ulcer	20 mg or 40 mg	Once daily for up to 6 months**
Zollinger-Ellison Syndrome	40 mg	Twice daily
***H. pylori* eradication (Triple therapy)**		
Esomeprazole	20 mg	Twice daily for 10 days
Amoxycillin	1 gm	Twice daily for 10 days
Clarithromycin	500 mg	Twice daily for 10 days

Pediatric

Indication	Dose	Frequency
1 to 11 years		
Short-term treatment of symptomatic GERD	10 mg	Once daily for up to 8 Weeks
12 to 17 years		
Short-term treatment of GERD	20 mg or 40 mg	Once daily for up to 8 Weeks

* The majority of patients are healed within 4 to 8 weeks. For patients who do not heal after 4-8 weeks, an additional 4-8 weeks treatment may be considered.
** Controlled studies did not extend beyond six months.
*** If symptoms do not resolve completely after 4 weeks, an additional 4 weeks of treatment may be considered

Injection

GERD-with Erosive Esophagitis	**Adult:** 20 mg or 40 mg once daily by intravenous injection (not less than 3 minutes) or intravenous infusion (10 minutes to 30 minutes). **Pediatric:** Give the following doses once daily as an intravenous infusion over 10 minutes to 30 minutes. ✣ 1 to 17 years: -Body weight less than 55 kg: 10 mg -Body weight 55 kg or greater: 20 mg ✣ 1 month to less than 1 year of age: 0.5 mg/kg

Direction for reconstitution of solution: Injection solution is prepared by adding 5 ml of 0.9% Sodium Chloride for intravenous injection into the vial containing the dry powder. The reconstituted solution should be stored at room temperature (up to 30^0 C) and administered within 12 hours after reconstitution.

Precaution

When prescribing esomeprazole with other antibiotics for eradication of *H.pylori*, risk of drug interaction should be considered. Esomeprazole should be use in caution in patient with severe Hepatic Renal Failure, Gastric Malignancy, Atrophic Gastritis, *Clostridium difficile* associated diarrhea.

Contraindication

Esomeprazole is contraindicated in patients with known hypersensitivity to any component of the formulation.

Side effect

In general, Esomeprazole was well tolerated in both short and long-term clinical trials. The most frequently occurring adverse events (>1%) are headache, diarrhea, nausea, flatulence, abdominal pain, constipation and dry mouth.

Use in pregnancy and lactation

Pregnancy: Esomeprazole has been assigned to pregnancy category B by the FDA. Animal studies have failed to reveal evidence of teratogenicity or fetal harm at therapeutic doses. Esomeprazole should be used in pregnancy if the potential benefit justifies the possible risk of the fetus.

Lactation: There is no adequate and well-controlled studies in pregnant woman. As Esomeprazole is likely to be excreted in human 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 inhibits gastric acid secretion. Therefore, Esomeprazole interferes with the absorption of drugs where gastric pH is an important determinant of bioavailability (e.g, Ketoconazole, iron salt and digoxin). Co-administration of oral contraceptives, diazepam, phenytoin or quinidine did not seem to change the pharmacokinetic profile of Esomeprazole. Co-administration of Esomeprazole, Clarithromycin and Amoxycillin has resulted in increased plasma levels of Esomeprazole and 14-hydroxyclarithromycin.

Overdose

There have been no reports of overdose with Esomeprazole. No specific antidote for Esomeprazole is known. Since Esomeprazole is extensively protein bound (97%), it is not expected to be removed by dialysis. In the event of overdosage, treatment should be symptomatic and supportive.

Storage

Store in a cool and dry place, protected from light. Keep out of the reach of the children.

Packaging:

Ema-20 Tablet: Each box contains 3 x 10 tablets in Alu-Alu blister strip.
Ema-40 Tablet: Each box contains 3 x 10 tablets in Alu-Alu blister strip.
Ema-20 Capsule: Each box contains 6 x 10 capsules in Alu-Alu blister strip.
Ema-40 Capsule: Each box contains 3 x 10 capsules in Alu-Alu blister strip.
Ema-40 IV Injection: Box containing one vial of sterile Esomeprazole Sodium BP equivalent to Esomeprazole 40 mg, one ampoule of 5 ml of 0.9% Sodium Chloride Injection BP with a 5 ml disposable syringe.

Manufactured by:

Globe

Globe Pharmaceuticals Ltd.

Noakhali, Bangladesh.