

Composition :

Emep[®]20 Capsule : Each capsule contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg as enteric coated pellets.

Emep[®]40 Capsule : Each capsule contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 40 mg as enteric coated pellets.

Emep[®] Tablet : Each enteric coated tablet contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Emep[®] IV Injection : Each vial contains lyophilized Esomeprazole Sodium INN equivalent to Esomeprazole 40 mg.

Pharmacology :

Esomeprazole is the S-isomer of Omeprazole, a proton pump inhibitor. Esomeprazole suppresses gastric acid secretion by specific inhibition of the H⁺/K⁺ATPase in the gastric parietal cell.

Indications :

Emep[®] Tablet/Capsule :

- For the treatment of heart burn and other symptoms associated with Gastroesophageal Reflux Disease
- For the healing of erosive esophagitis
- For maintenance of healing of erosive esophagitis
- In duodenal and gastric ulcer
- In combination with amoxicillin, clarithromycin, esomeprazole is used for the treatment of *H. pylori* infection and duodenal ulcer disease to eradicate *H. pylori*.

Emep[®] IV Injection :

Emep[®] IV injection is indicated for gastric antisecretory treatment when the oral route is not possible. Such as bleeding peptic ulcer, short-term treatment of Gastroesophageal Reflux Disease (Upto 10 days), erosive esophagitis, pre.and post operative hyperacidity and hyperacidity in patients with non-surgical NPO status.

Dosage & administration :

Emep[®] Tablet/Capsule :

Esomeprazole tablet / capsule should be taken one hour before meal.

Indications	Dose	Frequency
Symptomatic Gastroesophageal Reflux Disease	20 mg	Once daily for 4 weeks
Healing of Erosive Esophagitis	20 or 40 mg	Once daily for 4-8 weeks*
Maintenance of Healing of Erosive Esophagitis	20 mg	Once daily
Duodenal Ulcer	20 mg	Once daily for 2-4 weeks
Gastric Ulcer	20-40 mg	Once daily for 4-8 weeks
<i>H. pylori</i> eradication reduces the risk of duodenal ulcer recurrence		
Triple therapy		
Emep [®]	40 mg	Once daily for 10 days
Amoxicillin	1000 mg	Twice daily for 10 days
Clarithromycin	500 mg	Twice daily for 10 days

* 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.

Emep[®] IV Injection :

The recommended dose is either 20 mg or 40 mg Esomeprazole given once daily by intravenous injection (not less than 3 minutes) or intravenous infusion (10 to 30 minutes). Emep[®] IV injection should not be administered concomitantly with any other medications through the same intravenous site. Treatment with Emep[®] IV injection should be discontinued as soon as the patient is able to resume treatment with Emep[®] capsule / tablet.

Method of administration :

Injection :

Esomeprazole IV injection is obtained by adding 5 ml Sodium Chloride 0.9% injection to the vial containing powder. After reconstitution the injection should be given slowly over a period of at least 3 minutes. Half of the IV injection should be used when 20 mg is to be administered. The injection should be used within 12 hours after reconstitution and can be stored at room temperature.

Infusion :

Esomeprazole intravenous infusion is prepared by first reconstituting the content of vial with 5 ml of Sodium Chloride 0.9% injection or 5% dextrose injection and further diluting the resulting solution to a final volume of 50 ml. The reconstituted solution should be administered as an intravenous infusion over a period of 10-30 minutes. The reconstituted solution should be stored at room temperature and must be used within 12 hours when esomeprazole is dissolved in Sodium Chloride 0.9% injection and within 6 hours when dissolved in 5% dextrose.

Contraindications :

Esomeprazole is contraindicated in patients who have known hypersensitivity to esomeprazole or any component of the formulation.

Side effects :

In general, esomeprazole is well tolerated in both short and long term use. Adverse events reported with esomeprazole include headache, diarrhoea, nausea, flatulence, abdominal pain, constipation and dry mouth.

Precautions :

Geriatric patients : No dosage adjustment is necessary.

Renal insufficiency : No dosage adjustment is necessary.

Hepatic insufficiency : No dosage adjustment is necessary in patients with mild to moderate liver impairment. For patients with severe liver impairment a dose of 20 mg of esomeprazole should not be exceeded.

Use in special groups :

Use in pregnancy : This drug should be used during pregnancy only if clearly needed.

Use in lactation : 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.

Children : Children over 1 year are recommended to use oral esomeprazole.

Drug interactions :

Esomeprazole is extensively metabolized in the liver. Drug interactions studies have shown that esomeprazole does not have any clinically significant interactions with phenytoin, warfarin, quinidine, clarithromycin or amoxicillin. Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (e.g. ketoconazole, iron salts and digoxin).

Storage :

- Store below 30°C, keep in dry place & protect from light.
- The use of freshly reconstituted injection is recommended. However, the reconstituted injection may be stored for a maximum of 12 hours when stored at room temperature.
- Keep out of the reach of children.

Packing :

Emep[®]20 Capsule : Each box contains 60's capsules in Alu-Alu blister pack.

Emep[®]40 Capsule : Each box contains 40's capsules in Alu-Alu blister Pack.

Emep[®] Tablet : Each box contains 60's tablets in Alu-Alu blister pack.

Emep[®] IV Injection : Each box contains one vial of lyophilized Esomeprazole Sodium powder with 1 ampoule of 5 ml Sodium Chloride 0.9% Injection and 5 ml disposable syringe.