

**Composition:**

Esosil® 20mg capsule: Each capsule contains Esomeprazole Magnesium Trihydrate BP 22.27 mg equivalent to Esomeprazole 20 mg in enteric coated pellets.

Description:

Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H⁺/K⁺-ATPase, the 'proton Pump' of the gastric parietal cell.

Indications:

- Treatment of Gastroesophageal Reflux Disease (GERD)
- For the healing of Erosive Esophagitis
- In combination with Amoxicillin and Clarithromycin for eradication of *Helicobacter pylori* infection in patients with duodenal ulcer disease.
- Zollinger -Ellison Syndrome
- Acid related Dyspepsia
- Duodenal & Gastric ulcer

Dosage & Administration:

Indication	Dose	Frequency
Gastroesophageal Reflux Disease(GERD)		
Healing of erosive esophagitis	20 mg / 40 mg	Once daily for 4 - 8 weeks
H.pylori eradication(Triple therapy)		
Esosil®	20 mg	Twice daily for 10 days
Amoxicillin	1000 mg	Twice daily for 10 days
Clarithromycin	500 mg	Twice daily for 10 days
Others disease		
Zollinger-Ellison Syndrome	20 mg-80 mg	Once daily continued as long as clinically indicated
Acid related Dyspepsia	20 mg / 40 mg	Once daily for 2 - 4 weeks
Duodenal ulcer	20 mg	Once daily for 2 - 4 weeks
Gastric ulcer	20 mg / 40 mg	Once daily for 4 - 8 weeks

Side Effects:

The most frequently occurring adverse events reported with esomeprazole include headache, diarrhoea, nausea, flatulence, abdominal pain, constipation & dry mouth.

Use in Special Group:

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Animal studies have revealed no teratogenic effects.

Lactation: The excretion of esomeprazole in milk has not been studied. Breast-feeding should be therefore be discontinued if the use of esomeprazole is considered essential.

Paediatric use: Safety & effectiveness in paediatric patients have not been established.

Contraindications:

Esomeprazole is contraindicated in-patient with known hypersensitivity to any of the formulation.

Warning & Precautions :

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.

Drug Interactions:

Esomeprazole is extensively metabolized in the liver by CYP2C19 and CYP3A4. In vitro and in vivo studies shows that Esomeprazole is not likely to inhibit CYPs 1A2, 2A6, 2C9, 2D6, 2E1 and 3A4. No clinically relevant interactions with drugs metabolized by these CYP enzymes would be expected. Drug interaction studies have shown that Esomeprazole does not have any clinically significant interactions with phenytoin, warfarin, Quinidine, clarithromycin or amoxicillin.

Storage:

Store at temperature not exceeding 30° C in a dry place. Protect from light & moisture. Keep out of the reach of children.

Commercial Pack:

Esosil® 20mg capsule: Each box contains 10x10 capsules in Alu-Alu blister pack.

Manufactured by :
 **Silva**
Pharmaceuticals Limited
Majidde, Noakhali, Bangladesh