

Esogap[®]

Esomeprazole

Composition:

Esogap[®] 20 Tablet: Each enteric coated tablet contains Esomeprazole 20 mg as Esomeprazole Magnesium Trihydrate INN.

Esogap[®] 40 Tablet: Each enteric coated tablet contains Esomeprazole 40 mg as Esomeprazole Magnesium Trihydrate INN.

Description:

Esogap[®] is a preparation of Esomeprazole, which is the S-isomer of Omeprazole. It reduces gastric acid secretion through inhibition of proton pump in the parietal cell. It is administered as prodrug. In the liver it rapidly undergoes a molecular conversion to the active form, which forms a covalent disulphide bond with the H⁺,K⁺ATPase, irreversibly inactivating the enzyme.

Indication:

Treatment of:

- Gastroesophageal Reflux Disease (GERD)
- Peptic Ulcer Disease
 - H. Pylori-associated ulcer
 - NSAID-associated ulcer
 - Prevention of rebleeding from peptic ulcer
- Non ulcer dyspepsia
- Prevention of stress-Related mucosal bleeding
- Hypersecretory conditions e.g Gastrinoma and others.

Dosage and Administration:

1. Treatment of erosive oesophagitis: 20mg or 40mg once daily for 4 to 8 weeks. For patients who have not responded to the treatment, an additional course of Esomeprazole may be considered.
2. Long term management of oesophagitis: 20mg once daily with complication e.g. Barretts oesophagus patient may require twice daily dosing for at least 3 months.
3. Symptomatic GERD: 20mg once daily for 4 weeks.
4. H.Pylori associated duodenal ulcer: Treatment regimen consists of 14 days regimen of "triple therapy" : 20mg Esomeprazole, twice daily; Clarithromycin, 500mg twice daily; 1gm amoxicillin twice daily.

Contraindication:

Patients with known hypersensitivity to any component of the formulation.

Precautions:

Symptomatic response to therapy with Esomeprazole does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long term with Omeprazole, of which Esomeprazole is an s-isomer.

Drug Interactions:

Esomeprazole inhibits gastric acid secretion. Therefore, Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (e.g. Ketoconazole, Iron salts and Digoxin, Itraconazole, Atazanavir).

Side effect:

Esomeprazole is well tolerated and extremely safe. Diarrhoea, headache, and abdominal pain are reported in 1-5% of patients. Esomeprazole do not have teratogenicity in animal models, however safety during Pregnancy has not been established. A minor reduction in oral cyanocobalamin absorption occurs during proton pump inhibition, potentially leading to subnormal vitamin B₁₂ levels with prolonged therapy. Gastric bacterial concentration increase in patient taking proton pump inhibitor for prolonged period with unknown clinical significance. Hospitalized patient may have an increased risk for clostridium difficile infection. Rise in gastrin level may stimulate hyperplasia of ECL cells.

Use in Special Populations:

Geriatric: Dose adjustment is not necessary.

Paediatric: Safety and effectiveness in paediatric patients is not been established.

Hepatic insufficiency: No dose adjustment is recommended for patients with mild to moderate hepatic insufficiency. However, in patients with severe hepatic insufficiency a dose of 20 mg once daily should not be exceeded.

Renal insufficiency: Dose adjustment is not necessary.

Pregnancy: There are no adequate and well controlled studies in pregnant women. This drug should be used during pregnancy only if clearly indicated.

Lactation: The excretion of Esomeprazole in human milk has not been studied. Because Esomeprazole is likely to be excreted in human milk, a decision should be made whether to discontinue the drug.

Storage Condition:

Store in a dry place below 30° C. Protect from light and moisture.

Commercial packs

Esogap[®] 20 Tablet: Box containing 50 tablets in 5x 10's blister packs.

Esogap[®] 40 Tablet: Box containing 50 tablets in 5x 10's blister packs.



Manufactured by
EURO Pharma Ltd.
In Pursuit of Excellence
Shampur, Dhaka, Bangladesh

® Regd. Trademark