

Esohil

Esomeprazole USP

Composition: Esohil-20 Capsule: Each delayed release capsule contains enteric coated pellets of Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Esohil-40 Capsule: Each delayed release capsule contains enteric coated pellets of Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 40 mg.

Pharmacology: Esomeprazole, the S-isomer of Omeprazole, reduces gastric acid secretion through specific inhibition of the acid pump in the parietal cell, where it is concentrated and converted to the active form in the acid environment of the secretory canaliculi and inhibits the enzyme H⁺K⁺-ATPase in the acid pump. The effect of the final step of the gastric acid secretion is dose-dependent and provides effective inhibition of both basal and stimulated acid secretion. Food intake has no significant influence on the effect of esomeprazole on intragastric acidity.

Indication: Treatment of Gastroesophageal Reflux Disease (GERD), Healing of erosive esophagitis, Maintenance of healing of erosive esophagitis, Symptomatic relief of Gastroesophageal Reflux Disease (GERD), Risk reduction of NSAID associated gastric ulcer, *H. pylori* eradication (Triple therapy).

Dosage & Administration:

Capsule: Recommended adult dosage schedule of Esomeprazole

Indication	Dose	Frequency
Gastroesophageal Reflux Diseases (GERD)		
Healing of erosive esophagitis	20/40 mg	Once daily for 4 to 8 weeks *
Maintenance of healing of erosive esophagitis	20 mg	Once daily **
Symptomatic relief of GERD	20 mg	Once daily for 4 weeks ***
Risk reduction of NSAID associated gastric ulcers	20 mg	Once daily for upto. 6 months **
<i>H. pylori</i> eradication (Triple therapy)		
Esomeprazole	20 mg	Twice daily for 10 days
Amoxicillin	1000 mg	Twice daily for 10 days
Clarithromycin	500 mg	Twice daily for 10 days

Contraindication: Esomeprazole is contraindicated in those patients who have known hypersensitivity to any other components of the formulation.

Warning and Precautions:

Special Population: Geriatric: 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 should not be exceeded.

Precautions: Gender: No dosage adjustment is necessary.

Include 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.

Side Effect: Side effects reported with Esomeprazole include headache, diarrhea and abdominal pain.

Use In Pregnancy And Lactation:

US FDA Pregnancy Category: B

Teratology studies have been performed in animals and have revealed no evidence of impaired fertility or harm to the fetus due to Esomeprazole. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Because 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.

Use in Children & adolescents: 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 to 8 weeks, an additional 4 to 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.

Drug Interaction: Esomeprazole appears to be a selective inhibitor of the cytochrome P450 monooxygenase system, there may be an effect on hepatic clearance, but there have been no reports to date of clinically relevant interactions. There is some uncertainty over the effect of Esomeprazole on the oral combined contraceptive pill. Further assessment is currently underway. Physiological changes similar to those found with Omeprazole are likely to take place because of the reduction in gastric acid, which is likely to influence the bacterial colonization of the stomach and duodenum and also vitamin B₁₂ absorption.

Overdose: There is no experience to data with deliberate overdose. Data are limited but single doses of 80 mg Esomeprazole were uneventful. Esomeprazole is extensively plasma protein bound and is therefore not readily dialyzable. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilized.

Storage: Store in a cool (below 30 °C) and dry place, protect from light. Keep all medicines out of the reach of children.

How Supplied: Esohil-20 Capsule: Each box contains 6x10's capsules in Alu-Alu blister pack.

Esohil-40 Capsule: Each box contains 3x10's capsules in Alu-Alu blister pack.



Manufactured by:
Goodman Pharmaceuticals Ltd.
Better Health For All
Bhangnahati, Sreepur, Gazipur, Bangladesh

