Esotid®

Esomeprazole

Description: Esomeprazole (**Esotid®**) is the S-isomer of omeprazole, which is a mixture of the S-and R-isomers.

Composition
Esotid® 20 mg Tablet: Each enteric-coated tablet contains Esomeprazole Magnesium Trihydrate USP 22.21 mg equivalent to Esomeprazole 20 mg.
Esotid® 40 mg Tablet: Each enteric-coated tablet contains Esomeprazole Magnesium Trihydrate USP 44.42 mg equivalent to Esomeprazole 40 mg.
Esotid® 20 mg Capsule: Each capsule contains Esomeprazole Magnesium enteric coated pellets (23.5% w/w) 85.106 mg equivalent to Esomeprazole USP 20 mg.
Esotid® 40 mg Capsule: Each capsule contains Esomeprazole Magnesium enteric coated pellets (23.5% w/w) 170.213 mg equivalent to Esomeprazole USP 40 mg.

Mechanism of action: Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H^+/K^+-ATPase in the gastric parietal cell. The S-and R-isomers are protonated and converted in the acidic compartment of the parietal cell forming the active inhibitor. By acting specifically on the proton pump, esomeprazole blocks the final step in acid production, thus reducing gastric acidity. This effect is dose-related upto a daily dose of 20 to 40 mg and leads to inhibition of gastric acid secretion.

Pharmacokinetics: After oral administration peak plasma levels (C_{max}) occur at approximately 1.5 hours (T_{max}). The C_{max} increases proportionally when the dose is increased, and there is a three-fold increase in the area under the plasma concentration-time curve (AUC) from 20 to 40 mg. At repeated once daily dosing with 40 mg, the systemic bioavailability is approximately 90% compared to 64% after a single dose of 40 mg. Esomeprazole should be taken at least one hour before meals. Esomeprazole is 97% bound to plasma proteins. Esomeprazole is extensively metabolized in the liver by the cytochrome P450 (cyp) enzyme system.

Indications: Treatment of Gastro-esophageal Reflux Disease (GERD): Healing of erosive esophagitis, maintenance of healing of erosive esophagitis, symptomatic gastro-esophageal reflux disease. H. pylori eradication to reduce the risk of duodenal ulcer recurrence.

Dosage & administration
Recommended Adult Dosage Schedule of Esomeprazole:

Indications	Dose	Frequency
Gastro-esophageal Reflux Disease (GERD)		
Healing of erosive esophagitis	20 mg or 40 mg	Once Daily for 4 t0 8 Weeks*
Maintenance of healing of erosive esophagitis	20 mg	Once Daily **
Symptomatic gastro-esophageal reflux disease	20 mg	Once Daily for 4 Weeks ***
***H.pylori* eradication to reduce the risk of duodenal ulcer recurrence**		
Triple Therapy: **Esotid®** (Esomeprazole) **Moxin®** (Amoxicillin) Clarithromycin	 40 mg 1000 mg 500 mg	 Once Daily for 10 Days Twice Daily for 10 Days 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 for 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.

Side effects: Esomeprazole is well tolerated in both short and long-term clinical trials. The most frequently occurring adverse events are headache, diarrhoea, nausea, flatulence, abdominal pain, constipation, and dry mouth.

Contraindications: Esomeprazole is contraindicated in patients with known hypersensitivity to any component of the formulation or to substituted benzimidazoles. Clarithromycin is contraindicated in patients with a known hypersensitivity to any macrolide antibiotic.

Use in pregnancy & lactation: There are no adequate and well-controlled studies in pregnant women. Nursing mothers: The excretion of esomeprazole in milk has not been studied. 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.

Precautions: Proton pump inhibitors should be used with caution in liver disease, pregnancy and breast feeding. These may mask symptoms of gastric cancer; particular care is required in those whose symptoms change and in those over 45 years of age; the presence of gastric malignancy should be excluded before treatment. For patients with severe liver impairment, a dose of 20 mg should not be exceeded.

Overdosage: No specific antidote for esomeprazole is known. Since esomeprazole is extensively protein bound, it is not expected to be removed by dialysis. In the event of overdosage, treatment should be symptomatic and supportive.

Drug interactions: Esomeprazole is extensively metabolized in the liver. Co-administration of esomeprazole 30 mg and diazepam resulted in a 45% decrease in clearance of diazepam. 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). Co-administration of oral contraceptives, diazepam, phenytoin, or quinidine did not seem to change the pharmacokinetic profile of esomeprazole.

Storage: Keep out of reach of children. Store in a dry place, below 30˚C temperature and protected from light.

Packaging
Esotid® 20 mg Tablet: Each carton contains 14X7 tablets in blister pack.
Esotid® 40 mg Tablet: Each carton contains 14X3 tablets in blister pack.
Esotid® 20 mg Capsule: Each carton contains 10X9 capsules in blister pack.
Esotid® 40 mg Capsule: Each carton contains 10X6 capsules in blister pack.

Opsonin Pharma
Ideas for healthcare

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Manufactured by
Opsonin Pharma Limited
Rupatali, Barishal, Bangladesh.