

Esozol

Esomeprazole

COMPOSITION:

Esozol 20 Capsule: Each delayed release capsule contains enteric coated pellets of Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg.

Esozol 40 Capsule: Each delayed release capsule contains enteric coated pellets of Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 40 mg.

PHARMACOLOGY:

Esozol (Esomeprazole) is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H⁺/K⁺-ATPase in the gastric parietal cell. By acting specifically on the proton pump, **Esozol** blocks the final step in acid production, thus reducing gastric acidity.

INDICATION:

- Treatment of Gastroesophageal Reflux Disease (GERD)
- Healing of erosive esophagitis
- Maintenance of healing of erosive esophagitis
- Symptomatic Gastro esophageal Reflux Disease (GERD)
- Risk Reduction of NSAID-associated gastric ulcer
- *H. pylori* eradication (Triple therapy)

DOSAGE AND ADMINISTRATION:

Recommended adult dosage schedule of Esomeprazole:

Indication	Dose	Frequency
Gastro esophageal Reflux Disease (GERD)		
Healing of erosive esophagitis	20 mg or 40 mg	Once daily for 4 to 8 weeks*
Maintenance of healing of erosive esophagitis	20 mg	Once daily **
Symptomatic GERD	20 mg	Once daily for 4 weeks ***
Risk Reduction of NSAID- associated gastric ulcer	20 mg or 40 mg	Once daily for up to 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

Paediatric use (12 years and older)

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 4-8 weeks, an additional 4-8 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.

CONTRAINDICATION:

Esomeprazole is contraindicated in patients with known hypersensitivity to any component of the formulation or to substituted Benzimidazoles.

SIDE EFFECTS:

In general, Esomeprazole was well tolerated in both short- and long-term clinical trials. The most frequently occurring adverse events (>1%) are headache and diarrhea. Nausea, flatulence, abdominal pain, constipation and dry mouth occurred at similar rates among patients taking Esomeprazole.

PRECAUTION:

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 enantiomer.

USE IN PREGNANCY AND LACTATION:

Pregnancy: There are no adequate and well-controlled studies on the use of Esomeprazole in pregnant women. Therapeutic doses during pregnancy are unlikely to pose a substantial teratogenic risk. Esomeprazole should be used during pregnancy only if the potential benefit to pregnant women justifies the potential risk to the fetus.

Lactation: Esomeprazole is excreted in human milk. Thus, a decision should be taken to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

DRUG INTERACTION:

Drug interaction studies have shown that Esomeprazole does not have any clinically significant interactions with Phenytoin, Warfarin, Quinidine, Clarithromycin or Amoxicillin. Esomeprazole inhibits gastric acid secretion. Therefore, Esomeprazole may interfere with the absorption of drugs where gastric P^H is an important determinant of bioavailability (eg, Ketoconazole, Iron salts and Digoxin). Co-administration of oral contraceptives, Diazepam, Phenytoin or Quinidine did not seem to change the pharmacokinetic profile of Esomeprazole.

PHARMACEUTICAL PRECAUTION: It should be stored in a cool and dry place, protected from light and moisture.

HOW SUPPLIED:

Esozol 20 Capsule: Each box contains 6x10 capsules in Alu-Alu blister pack.

Esozol 40 Capsule: Each box contains 3x10 capsules in Alu-Alu blister pack.

Manufactured by:

MEDICON Pharmaceuticals Ltd.
Mirpur, Dhaka, Bangladesh