

Esolok

Esomeprazole

Composition:

Esolok 20 capsule: Each capsule contains enteric coated pellets of esomeprazole magnesium trihydrate BP equivalent to esomeprazole 20 mg.

Esolok 40 capsule: Each capsule contains enteric coated pellets of Esomeprazole magnesium trihydrate BP equivalent to esomeprazole 40 mg.

Esolok 20 tablet: Each enteric coated tablet contains esomeprazole magnesium trihydrate BP equivalent to esomeprazole 20 mg.

Esolok 40 tablet: Each enteric coated tablet contains esomeprazole magnesium trihydrate BP equivalent to esomeprazole 40 mg.

Esolok IV injection: Each vial contains sterile Esomeprazole Sodium INN equivalent to 40 mg Esomeprazole.

Description:

Esolok 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, Esolok blocks the final step in acid production thus reducing gastric acidity.

Indication:

Esolok (Esomeprazole) is indicated

- for the healing of erosive esophagitis
- for the maintenance of healing of erosive esophagitis
- for symptomatic gastroesophageal reflux disease
- for the eradication of Helicobacter pylori in combination with amoxicillin and clarithromycin
- for the risk reduction of NSAID induced gastric ulcer

Dosage and Administration:

Indication	Dosage	Frequency
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 Gastroesophageal Reflux Disease	20 mg	Once daily for 4 weeks**
Risk reduction of NSAID induced Gastric Ulcer	20 mg or 40 mg	Once daily for up to 6 month
Eradication of Helicobacter pylori in combination with Amoxicillin and Clarithromycin.		
Esolok (Esomeprazole) Amoxicillin and 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 of treatment may be considered.

** If symptoms do not resolve completely after 4 weeks, an additional 4 weeks of treatment may be considered.

Contraindication:

Esomeprazole is contraindicated in those patients who have known hypersensitivity to any component of the formulation.

Use in Pregnancy:

There are no adequate and well-controlled studies with esomeprazole in pregnant women. This drug may be used during pregnancy (as it is Pregnancy Category C) only if clearly needed.

Use in Nursing Mother:

The excretion of esomeprazole in human breast milk has not been studied. As esomeprazole is likely to be excreted in human breast 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.

Side Effect:

Headache, abdominal pain, diarrhoea, flatulence, nausea or vomiting etc.

Precaution:

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. For patient with severe liver impairment, a dose of 20 mg of esomeprazole should not be exceeded.

Drug Interaction:

Esomeprazole potentially can increase the concentration of diazepam in blood by decreasing the elimination of diazepam in the liver. The absorption of certain drugs may be affected by stomach acidity. Therefore, esomeprazole and other PPIs that reduce stomach acid also reduce the absorption and concentration of ketoconazole and increase the absorption and concentration of digoxin in blood. This may lead to reduced effectiveness of ketoconazole or increased digoxin toxicity respectively.

Presentation:

Esolok 20 capsule : Each box contains 10 x 10's capsules in Alu-Alu blister pack.

Esolok 40 capsule : Each box contains 4 x 12's capsules in Alu-Alu blister pack.

Esolok 20 tablet : Each box contains 10 x 10's tablets in Alu-Alu blister pack.

Esolok 40 tablet : Each box contains 3 x 10's tablets in Alu-Alu blister pack.

Esolok IV injection: Each combipack contains 1 vial of 40 mg Esomeprazole and 1 ampoule of 5 ml water for Injection.

**Manufactured by:**

The IBN SINA Pharmaceutical Industry Ltd.
Shafipur, Gazipur, Bangladesh.