

Composition:

Esoclip capsule: Each capsule contains Esomeprazole USP 20 mg.

Pharmacology:

Esomeprazole is a PPI that suppresses gastric acid secretion by inhibiting H+/K+ ATPase in the gastric parietal cell. It is the S-isomer of omeprazole.

Indications and Uses:

Esomeprazole is indicated for the following diseases:

- Treatment of Gastroesophageal Reflux Disease (GERD)
- Healing of Erosive Esophagitis
- Maintenance of Healing of Erosive Esophagitis
- Symptomatic Gastroesophageal Reflux Disease
- Risk Reduction of NSAID-Associated Gastric Ulcer
- H. pylori Eradication to Reduce the Risk of Duodenal Ulcer
- Pathological Hypersecretory Conditions Including
- Zollinger-Ellison Syndrome

Dosage and Administration:

Esomeprazole USP 20mg Capsule		
Indication	Dose	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
Pediatric treatment (12 to 17 Year Olds)		
Healing of Erosive Esophagitis	20 mg or 40 mg	Once Daily for 4 to 8 Weeks
Symptomatic GERD	20 mg	Once Daily for 4 Weeks
1 to 11 Year Olds+ Short-term Treatment of Symptomatic GERD	10 mg	Once Daily for up to 8 Weeks
weight < 20 kg	10 mg	Once Daily for 8 Weeks
weight ≥ 20 kg	10 mg or 20 mg	Once Daily for 8 Weeks

Contraindications:

Hypersensitivity to any component of the formulation, substituted benzimidazoles, or other proton pump inhibitors.

Warning & Precautions:

Esomeprazole should be given with caution in patients with renal impairment, liver disease, in pregnancy and in breast-feeding. Proton-pump inhibitors 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.

Drug Interactions:

Esomeprazole may interact with Benzodiazepines, Digoxin, Iron salts etc.

Overdose Effects:

There is no experience to data with deliverate 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 utilised.

Side Effects:

Common side effects include headache, diarrhea, nausea, gas, decreased appetite, constipation, dry mouth, and abdominal pain. More severe side effects are severe allergic reactions, chest pain, dark urine, fast heartbeat, fever, persistent sore throat, severe stomach pain, unusual bruising or bleeding, unusual tiredness, and yellowing of the eyes or skin.

Use in Pregnancy and Lactation:

Pregnancy Category B. There is no contraindication in pregnancy and lactation.

Storage Conditions:

Store below 30°C temperature, dry place and away from light. Keep all medicine out of the reach of children.

How Supplied:

Esoclip Capsule: Each box containing 5x10's Capsule in blister packs.

