

Opton®

Esomeprazole
Tablet/IV Injection

Description

Esomeprazole is the S-isomer of Omeprazole. It reduces gastric acid secretion through a specific targeted mechanism of action. It is a specific inhibitor of the acid pump in the parietal cell.

Indications

1. Healing of erosive esophagitis.
2. Long-term management of esophagitis.
3. Symptomatic gastroesophageal reflux disease (GERD).
4. In combination with antibacterials for treatment of duodenal ulcer associated with *H. pylori* (Triple therapy with Esomeprazole, Clarithromycin and Amoxicillin).

Dosage and Administration

Opton® Tablet

Healing of erosive esophagitis: 20 mg or 40 mg once daily for 4 to 8 Weeks. For those patients who have not healed after 4-8 weeks of treatment, an additional 4-8 weeks course of Esomeprazole may be considered.

Long-term management of esophagitis: 20 mg once daily.

Symptomatic gastroesophageal reflux disease: 20 mg once daily for 4 weeks.

H. pylori eradication for treatment of duodenal ulcer: Triple therapy: 20 mg Esomeprazole once daily with 500 mg Clarithromycin twice daily, and 1 g Amoxicillin twice daily for 7-10 days.

Opton® 40 IV Injection

The recommended adult dose in GERD with Erosive Esophagitis is either 20 or 40 mg Esomeprazole given once daily by intravenous injection (no less than 3 minutes) or intravenous infusion (10 to 30 minutes).

Pediatric dose (1 to 11 years old): Short term treatment of symptomatic GERD: 10 mg once daily for up to 8 weeks.

Healing of erosive esophagitis: Weight <20 kg: 10 mg once daily for up to 8 weeks.
Weight ≥20 kg: 10 mg or 20 mg once daily for

up to 8 weeks.

Preparations for Use and Administration of Opton® 40 IV Injection: A solution for intravenous infusion is prepared by first reconstituting the contents of one vial with 5 ml of 0.9% Sodium Chloride BP and further diluting the resulting solution to a final volume of 50 ml. The resultant concentration after diluting to a final volume of 50 ml is 0.8 mg/ml.
20 mg dose: Withdraw 25 ml of the final solution and administer as an intravenous infusion over 10 minutes to 30 minutes.

10 mg dose: Withdraw 12.5 ml of the final solution and administer as an intravenous infusion over 10 minutes to 30 minutes.

Contraindications

Patients with known hypersensitivity to any component of the formulation.

Adverse Reactions

In general, Esomeprazole is well tolerated in both short and long-term use. Common adverse effects are headache and diarrhoea. Other side effects include nausea, flatulence, abdominal pain, constipation, and dry mouth.

Use in Special Population

Geriatric: Dosage adjustment is not necessary.

Pediatric: Safety and effectiveness in pediatric patients have not been established.

Hepatic insufficiency: No dosage adjustment is recommended for patients with mild to moderate hepatic insufficiency. However, in patients with severe hepatic insufficiency a dose of 20 mg once daily should not be exceeded.

Renal insufficiency: Dosage adjustment is not necessary.

Pregnancy: There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.

Nursing mothers: The excretion of Esomeprazole in human milk has not been studied. Because Esomeprazole is likely to be

excreted in human milk, a decision should be made whether to discontinue the drug.

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 utilised.

Drug Interactions

Esomeprazole inhibits gastric acid secretion. Therefore, Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (eg, Ketoconazole, Iron salts and Digoxin).

Pharmaceuticals Precautions

Store in a cool & dry place.

Commercial Pack

Opton® Tablet: Box containing 60 tablets in 6 x 10's Alu-Alu form pack. Each tablet contains Esomeprazole Magnesium USP equivalent to Esomeprazole 20 mg.

Opton® 40 Tablet: Box containing 30 tablets in 3 x 10's Alu-Alu form pack. Each tablet contains Esomeprazole Magnesium USP equivalent to Esomeprazole 40 mg.

Opton® 40 IV Injection: Each commercial box containing one vial of sterile lyophilized powder of Esomeprazole Sodium INN equivalent to Esomeprazole 40 mg, one ampoule of 0.9% Sodium Chloride BP 5 ml and one sterile disposable syringe (5 ml).



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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