

ESORAL®

Esomeprazole capsule, enteric coated tablet and IV injection

DESCRIPTION

Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of H₊/K₊-ATPase in the gastric parietal cell. Esomeprazole blocks the final step in acid production thus reduces gastric acidity. This effect is dose related up to a daily dose of 20 to 40 mg and leads to inhibition of gastric acid secretion. **Esoral®** Enteric Coated Tablet is a preparation of Esomeprazole Magnesium USP. **Esoral®** Capsule contains enteric coated pellets of Esomeprazole Magnesium USP. **Esoral® 40** IV Injection is a combination pack consisting of a vial containing lyophilized powder of Esomeprazole Sodium and a separate ampoule of 5 ml Sodium Chloride BP 0.9% Injection as reconstituting solution.

INDICATIONS

Gastroesophageal Reflux Disease (GERD)

- Treatment of Erosive Esophagitis
 - Long-term management of patients with healed Esophagitis to prevent relapse
 - Symptomatic treatment of Gastroesophageal Reflux Disease (GERD)
- Eradication of *Helicobacter pylori* in combination with appropriate antibiotics**
- Healing of *H. pylori* associated duodenal ulcer
 - Prevention of relapse of peptic ulcer in patients with *H. pylori* associated ulcer

DOSAGE AND ADMINISTRATION

Indication	Dose and frequency
Healing of Erosive Esophagitis	20-40 mg once daily for 4-8 weeks. If not healed an additional 4-8 weeks of treatment may be considered
Maintenance of healing of Erosive Esophagitis	20 mg once daily (controlled studies have not exceeded 6 months)
Symptomatic Gastroesophageal Reflux Disease(GERD)	20 mg once daily for 4 weeks. If symptoms persist an additional 4 weeks of treatment may be considered
Eradication of <i>H. pylori</i> to reduce the risk of duodenal ulcer recurrence	10 days of triple therapy with Esomeprazole 40 mg once daily, amoxicillin 1 g twice daily and clarithromycin 500 mg twice daily is recommended
Children: Short term treatment of GERD	<ul style="list-style-type: none">• 1 to 11 years: 10 mg once daily upto 8 weeks• 12 to 17 years: 20/40 mg once daily upto 8 weeks

Injection

Gastroesophageal Reflux Disease (GERD)

For short-term treatment of adult GERD patients with a history of Erosive Esophagitis (EE) as an alternative to oral therapy. Treatment with **Esoral® 40** IV injection should be discontinued as soon as the patient is able to continue treatment with Esoral tablet or capsule.

Indication	Dose and frequency
GERD with a history of Erosive Esophagitis	20 or 40 mg Esomeprazole once daily

Safety and efficacy of **Esoral® 40** IV Injection as a treatment of GERD patients with a history of Erosive Esophagitis for more than 10 days have not been demonstrated.

Directions for reconstitution of solution:

Solution for intravenous injection is prepared by adding 5 ml Sodium Chloride BP 0.9% injection into the vial containing the lyophilized powder of Esomeprazole Sodium.

Administration:

IV injection must be administered intravenously over a period of at least 3 minutes. Half of the IV injection should be used when 20 mg is to be administered. Prepared solution must be used within 12 hours of preparation and can be exposed to normal indoor lighting at a maximum of 30 °C.

Impaired renal function: No dosage adjustment is necessary in patients with mild, moderate or severe renal insufficiency.

Impaired hepatic function: No dosage adjustment is necessary in mild or moderate hepatic impairment. For patients with severe hepatic impairment, the dose should not exceed 20 mg.

Elderly : No dosage adjustment is necessary.

CONTRAINDICATIONS

It is contraindicated in patients with known hypersensitivity to Esomeprazole or to substituted benzimidazoles.

PRECAUTIONS

In the presence of any alarming symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melena) and when gastric ulcer is suspected or present. The possibility of malignancy should be excluded. Because treatment with Esomeprazole may alleviate symptoms and delay diagnosis, patients on long-term treatment should be kept under regular surveillance. When prescribing Esomeprazole with other antibiotics for *H. pylori* eradication, risk of drug interaction should be considered.

USE IN PREGNANCY AND LACTATION

Pregnancy

FDA approved pregnancy category B.

Nursing mothers

There are no data on the excretion of Esomeprazole into human milk.

SIDE-EFFECTS

The safety of Esomeprazole was evaluated worldwide in over 10000 patients (aged 18-84 years). In clinical trials the most frequently occurring adverse events were headache, diarrhoea, nausea, flatulence, abdominal pain and constipation. Rarely dermatitis, pruritis, urticaria, dizziness and dry mouth reported.

PHARMACEUTICAL PRECAUTION

Tablet & IV Injection:

Store in a dry place, away from light. Keep out of reach of children.

Capsule

Store in a dry place, below 25 °C temperature, away from light. Keep out of reach of children.

PACKAGING

Esoral® 20 Tablet: Box containing 8 strips of 14 tablets each. Each enteric coated tablet contains Esomeprazole Magnesium USP equivalent to Esomeprazole 20 mg.

Esoral® 40 Tablet: Box containing 3 strips of 10 tablets each. Each enteric coated tablet contains Esomeprazole Magnesium USP equivalent to Esomeprazole 40 mg.

Esoral® 40 IV Injection: Box containing one vial of sterile Esomeprazole Sodium INN equivalent to Esomeprazole 40 mg (as lyophilized powder) and one ampoule of 5 ml Sodium Chloride BP 0.9% Injection.

Esoral® 20 Capsule in HPMC shell: Box containing 6 strips of 10 capsules each. Each capsule contains Esomeprazole Magnesium USP equivalent to Esomeprazole 20 mg (as enteric coated pellets) in HPMC shell.

Esoral® 40 Capsule in HPMC shell: Box containing 5 strips of 6 capsules each. Each capsule contains Esomeprazole Magnesium USP equivalent to Esomeprazole 40 mg (as enteric coated pellets) in HPMC shell.



Manufactured by

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