Esomep®

Esomeprazole

Description

Esomep® is a preparation of Esomeprazole which is the S-isomer of Omeprazole, a proton pump inhibitor, weak base in nature and is concentrated and converted to the active form in the highly acidic environment of the intracellular canaliculi within the parietal cell, where it inhibits the enzyme H^+/K^+-ATPase, the acid pump. This effect on the final step of the gastric acid formation process is dose-dependent and provides for highly effective inhibition of both basal and stimulated acid secretion, irrespective of the stimulus.

Indications

Esomep® is indicated for:

- **Treatment of gastroesophageal reflux disease (GERD)**
  - Healing of erosive esophagitis
  - Maintenance of healing of erosive esophagitis
  - Symptomatic treatment of gastroesophageal reflux disease (GERD)
- **Risk reduction of NSAID-associated gastric ulcer**
  - Healing of gastric ulcers associated with NSAID therapy
  - Prevention of gastric and duodenal ulcers associated with NSAID
- ***H. pylori* eradication to reduce the risk of duodenal ulcer recurrence**
  - Healing of *H. pylori* associated duodenal ulcer
  - Prevention of relapse of peptic ulcers in patient with *H. pylori* associated
- **Pathological hypersecretory conditions including Zollinger-Ellison Syndrome**

Dosage and administration

Esomep® tablet and capsule

The recommended adult dosages outlined in the table below**. Esomep®** tablet and capsule should be taken one hour before meal.

Indication	**Dose**	**Frequency**
Gastroesophageal 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 treatment of gastroesophageal reflux disease (GERD)	20 mg	Once daily for 4 weeks***
Risk reduction of NSAID-associated gastric ulcer	20 mg or 40mg	Once daily for up to 6 months**
***H. pylori* eradication to reduce the risk of duodenal ulcer recurrence (triple therapy)**		
- **Esomep®**	40 mg	Once daily for 10 days
- Amoxicillin	1000 mg	Twice daily for 10 days
- Clarithromycin	500 mg	Twice daily for 10 days
Pathological hypersecretory conditions including Zollinger-Ellison Syndrome	40 mg	Twice daily

Pediatric GERD	**Dose**	**Frequency**
- 12 to 17 year olds (Short term treatment of GRED)	20 mg or 40 mg	Once daily for up to 8 weeks
- 1 to 11 year olds+ (weight ≥ 20 kg) (Healing of Erosive Esophagitis)	10 mg or 20 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 of 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.

+ Doses over 1 mg/kg/day have not been studied.

Esomep® IV injection for GERD patients with Erosive Esophagitis (EE)

Adult	Dose	Administration time
Over 18 years	20 mg or 40 mg	IV injection: > 3 minutes IV infusion: 10-30 minutes

Pediatric patients (1 years to 17 years)	Dose	Administration time
- Body weight less than 55 kg	10 mg	IV infusion over 10-30 minutes
- Body weight 55 kg or greater	20 mg	IV infusion over 10-30 minutes
Pediatric patients (1 month to less than 1 year of age)	0.5 mg/kg	IV infusion over 10-30 minutes

Direction for use of intravenous injection

Solution for injection should be prepared by adding 5 ml 0.9% w/w Sodium Chloride BP into the vial containing the powder. The reconstituted solution for injection is clear and colorless to very slightly yellow.

The reconstituted solution should be given as an intravenous injection over a period of at least 3 minutes. Half of the IV injection should be used when 20 mg is to be administrated. Use only freshly prepared solution. The reconstituted solution should be stored at room temperature (below 30°C) and should be administered within 12 hours after reconstitution. No refrigeration is required.

Patients with impaired hepatic function: No dosage adjustment is necessary in patients with mild to moderate liver impairment. For patients with severe liver impairment a dose of 20 mg of **Esomep®** should not be exceeded.

Patients with renal impairment: No dose adjustment is necessary in patients with impaired renal function.

Use in pregnancy & lactation

Pregnancy category B. Animal studies have revealed no teratogenic effects. No sufficient clinical data is available on exposed pregnancies for Esomeprazole. So, caution should be exercised when prescribing to pregnant women. It is not known whether Esomeprazole is excreted in human breast milk. Therefore Esomeprazole should not be used during breast-feeding.

Precautions

Symptomatic response to therapy with Esomeprazole does not preclude the presence of gastric malignancy. When gastric ulcer is suspected or present, malignancy should be excluded, as treatment with Esomeprazole may alleviate symptoms and delay diagnosis. When prescribing Esomeprazole for eradication of *H. pylori* possible drug interactions for all components in the triple therapy should be considered.

Side effects

The most commonly reported side effects were nausea, vomiting, abdominal pain, flatulence, diarrhoea, constipation and headache. Less frequent side-effects include dry mouth, peripheral edema, dizziness, sleep disturbances, fatigue, paraesthesia, arthralgia, myalgia, rash, and pruritus. Other side-effects reported rarely or very rarely include taste disturbance, stomatitis, hepatitis, jaundice, hypersensitivity reactions (including anaphylaxis, bronchospasm), fever, depression, hallucinations, confusion, gynaecomastia, interstitial nephritis, hyponatraemia, blood disorders (including leucopenia, leucocytosis, pancytopenia, thrombocytopenia), visual disturbances, sweating, photosensitivity, alopecia, Stevens-Johnson syndrome, and toxic epidermal necrolysis.

Contraindications

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

Overdosage

There is very limited experience to date with deliberate overdose. The symptoms described in connection with 280 mg were gastrointestinal symptoms and weakness. Single doses of 80 mg Esomeprazole were uneventful. No specific antidote is known. 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 utilized.

Drug interactions

Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (e.g., ketoconazole, iron salts and digoxin). Coadministration of atazanavir with Esomeprazole is expected to substantially decrease atazanavir plasma concentrations and thereby reduce its therapeutic effect. Esomeprazole inhibits CYP2C19, the major Esomeprazole metabolising enzyme. Thus, when Esomeprazole is combined with drugs metabolised by CYP2C19, such as diazepam, citalopram, imipramine, clomipramine, phenytoin etc., the plasma concentrations of these drugs may be increased and a dose reduction could be needed.

Pharmaceutical Precautions

Esomep® capsule and tablet: Store in a cool & dry place. Protect from light.

Esomep® IV injection: Store in a cool (below 30°C) & dry place. Protect from light.

Presentation

Esomep® 20 mg tablet: Each enteric coated tablet contains Esomeprazole 20 mg as Magnesium Trihydrate USP.

Esomep® 40 mg tablet: Each enteric coated tablet contains Esomeprazole 40 mg as Magnesium Trihydrate USP.

Esomep® 20 mg capsule: Each capsule contains Esomeprazole 20 mg as Magnesium Trihydrate USP in enteric coated pellets.

Esomep® 40 mg capsule: Each capsule contains Esomeprazole 40 mg as Magnesium Trihydrate USP in enteric coated pellets.

Esomep® 40 mg lyophilized powder for injection: Each vial contains Esomeprazole 40 mg as Sodium INN.

Package quantities

Esomep® 20 mg tablet: Cartons of 50 tablets in blister.

Esomep® 40 mg tablet: Cartons of 30 tablets in blister.

Esomep® 20 mg capsule: Cartons of 50 capsules in blister.

Esomep® 40 mg capsule: Cartons of 40 capsules in blister.

Esomep® 40 mg IV Injection: Carton containing 1 vial of 40 mg lyophilized Esomeprazole, 1 ampoule of 5 ml Salinor® (0.9% w/v Sodium Chloride BP) as diluent.

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