

Esoable 40 Injection

Esomeprazole (40 mg) Injection

Composition:

Each vial contains:

- **Esomeprazole Sodium equivalent to Esomeprazole 40 mg**

Pharmacological Class:

- **Proton Pump Inhibitor (PPI)**

Indications:

Esomeprazole injection is used for:

- **Treatment of gastroesophageal reflux disease (GERD) with erosive esophagitis in patients unable to take oral therapy.**
- **Prevention and treatment of NSAID-induced gastric ulcers in high-risk patients.**
- **Zollinger-Ellison syndrome and other hypersecretory conditions.**
- **Short-term management of gastric acid-related conditions requiring rapid acid suppression.**
- **Prevention of rebleeding in patients with peptic ulcer bleeding (in combination with endoscopic therapy).**

Mechanism of Action:

Esomeprazole inhibits the H⁺/K⁺ ATPase enzyme system (proton pump) in the gastric parietal cells. This reduces the secretion of gastric acid, aiding in ulcer healing and symptom relief in acid-related disorders.

Dosage and Administration:

- **Adults:**
 - **Standard dose: 40 mg once daily via intravenous (IV) injection or infusion.**
 - **For Zollinger-Ellison syndrome: Dose may be adjusted based on the patient's condition and response.**
 - **For prevention of rebleeding in peptic ulcer: 80 mg IV bolus followed by 8 mg/hour continuous infusion for 72 hours.**

Method of Administration:

- **Injection: Reconstitute the vial with 5 ml of 0.9% sodium chloride and administer slowly over at least 3 minutes.**
- **Infusion: Reconstitute with appropriate volume of 0.9% sodium chloride or 5% dextrose for a diluted concentration and infuse over 10–30 minutes.**

Contraindications:

- **Hypersensitivity to Esomeprazole, substituted benzimidazoles, or any excipients in the formulation.**
- **Concomitant use with medications like nelfinavir (due to interaction concerns).**

Warnings and Precautions:

- **Bone Fractures: Long-term use of PPIs may increase the risk of fractures, especially in high doses.**
- **Clostridioides difficile Infection: Use cautiously in patients with diarrhea; prolonged use may increase risk.**
- **Vitamin B12 Deficiency: Chronic use may lead to malabsorption of Vitamin B12.**
- **Renal and Liver Impairment: Dose adjustment may be required in severe liver dysfunction.**
- **Hypomagnesemia: Prolonged use may lead to low magnesium levels; monitor patients regularly.**
- **Pregnancy and Breastfeeding:**
 - **Pregnancy Category B: Use only if clearly needed under medical supervision.**
 - **Breastfeeding: Limited data; consult a healthcare provider before use.**

Side Effects:

Common side effects:

- **Headache**
- **Nausea**

- **Injection site reactions (e.g., pain, swelling, redness)**
- **Diarrhea or constipation**

Rare but serious side effects:

- **Hypersensitivity reactions (rash, itching, swelling)**
- **Severe abdominal pain (indicative of acute pancreatitis or other serious conditions)**
- **Low magnesium levels (manifested as muscle spasms, irregular heartbeat)**

Drug Interactions:

- **Clopidogrel: Esomeprazole may reduce the effectiveness of clopidogrel.**
- **Warfarin: May increase the risk of bleeding; monitor INR closely.**
- **Digoxin and Methotrexate: Increased levels with Esomeprazole; monitor toxicity.**

Storage:

- **Store below 25°C in a dry place, protected from light.**
- **Reconstituted solutions should be used immediately; if not, store at 2–8°C and use within 12 hours.**

Packaging:

- **Supplied in sterile vials for single use, with necessary diluent or preparation instructions.**

Manufacturer:

- **[Manufacturer Name]**

Note:

This medication should only be administered by a healthcare professional. Monitor patients for side effects, and discontinue use if severe reactions occur. Ensure proper reconstitution and handling to maintain sterility and efficacy.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113