# Information For the User Esomeprazole (40mg)

# **Esoable 40 Tablet**

# Esomeprazole (40 mg) Tablet

# **Composition:**

**Each tablet contains:** 

 Esomeprazole Magnesium equivalent to Esomeprazole 40 mg

# **Pharmacological Class:**

Proton Pump Inhibitor (PPI)

#### **Indications:**

Esomeprazole 40 mg tablets are used for the treatment and management of:

- Gastroesophageal reflux disease (GERD) with or without erosive esophagitis
- Zollinger-Ellison syndrome and other hypersecretory conditions
- Prevention and treatment of NSAID-induced gastric ulcers
- Maintenance therapy for healed erosive esophagitis
- Helicobacter pylori eradication (in combination with antibiotics) to reduce the risk of duodenal ulcer recurrence
- Relief of acid-related dyspepsia

#### **Mechanism of Action:**

Esomeprazole is a proton pump inhibitor that specifically targets and inhibits the H+/K+ ATPase enzyme in gastric parietal cells, reducing gastric acid secretion. It provides prolonged acid suppression, promoting healing of ulcers and relief from acid reflux symptoms.

#### **Dosage and Administration:**

- Adults and adolescents over 12 years:
  - o GERD with erosive esophagitis: 40 mg once daily for 4-8 weeks.
  - Maintenance therapy for healed erosive esophagitis: 20-40 mg once daily.
  - Zollinger-Ellison syndrome: Individualized dosage, starting from 40 mg twice daily.

- NSAID-induced ulcer prevention: 20-40 mg once daily.
- Children under 12 years: Consult a healthcare provider for age-appropriate dosage.
- Take the tablet at least 1 hour before a meal.
  Swallow whole with water; do not chew or crush.

#### **Contraindications:**

- Hypersensitivity to Esomeprazole, substituted benzimidazoles, or any component of the formulation.
- Concomitant use with medications like nelfinavir or rilpivirine.

#### **Warnings and Precautions:**

- Long-Term Use: Chronic use may lead to an increased risk of bone fractures, particularly in the hip, wrist, or spine.
- Clostridioides difficile Infection: Risk of diarrhea; use cautiously in patients with severe diarrhea or colitis.
- Vitamin B12 Deficiency: Long-term use may impair B12 absorption. Monitor and supplement as needed.
- Hypomagnesemia: Prolonged use may result in low magnesium levels; monitor in at-risk patients.
- Liver Impairment: Dose adjustment may be needed in severe liver dysfunction.
- Pregnancy and Breastfeeding:
  - Pregnancy Category B: Use only if clearly necessary and under medical supervision.
  - Breastfeeding: Limited data on excretion in breast milk; consult a healthcare provider.

#### **Side Effects:**

# **Common side effects:**

- Headache
  - Nausea
  - Diarrhea or constipation
  - Abdominal pain

Flatulence

#### Rare but serious side effects:

- Allergic reactions (rash, itching, swelling)
- Severe hypomagnesemia (e.g., muscle spasms, irregular heartbeat)
- Severe skin reactions like Stevens-Johnson syndrome (rare)

# **Drug Interactions:**

- Clopidogrel: Esomeprazole may reduce its effectiveness.
- Warfarin: Increased risk of bleeding; monitor INR closely.
- Methotrexate: May increase serum methotrexate levels.
- Digoxin: Increased levels; monitor for toxicity.

# **Storage:**

- Store at a temperature not exceeding 25°C in a dry place, protected from light and moisture.
- Keep out of reach of children.

#### Packaging:

• Available in blister packs of 10, 20, or 30 tablets.

#### Note:

This medication should be taken as prescribed by a healthcare provider. Do not discontinue abruptly without consulting a doctor. If symptoms persist or unusual side effects occur, seek medical advice promptly.

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

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