ESOMEPRAZOLE

Class: Proton Pump Inhibitor , substituted benzimidazole

Indications: Oral: Short-term (4-8 weeks) treatment of erosive esophagitis; maintaining symptom resolution and healing of erosive esophagitis; treatment of symptomatic gastroesophageal reflux disease (GERD); as part of a multidrug regimen for *Helicobacter pylori* eradication in patients with duodenal ulcer disease (active or history of within the past 5 years); prevention of gastric ulcers in patients at risk (age ≥60 years and/or history of gastric ulcer) associated with continuous NSAID therapy; long-term treatment of pathological hypersecretory conditions including Zollinger-Ellison syndrome

Canadian labeling: Additional use (not in U.S. labeling): Oral: Treatment of nonerosive reflux disease (NERD); treatment of NSAID-induced gastric ulcers.
I.V.: Short-term (≤10 days) treatment of gastroesophageal reflux disease (GERD) when oral therapy is not possible or appropriate.

Available dosage form in the hospital:

ESOMEPRAZOLE 20MG TAB, ESOMEPRAZOLE 40MG TAB, ESOMEPRAZOLE 40MG VIAL, ESOMEPRAZOLE 40MG INFUSION

Trade Names:

Dosage: Adult

Note: All dosing is expressed in terms of esomeprazole base, regardless of the salt associated with the dosing information. Esomeprazole strontium 24.65 mg is equivalent to 20 mg of esomeprazole base; esomeprazole strontium 49.3 mg is equivalent to 40 mg of esomeprazole base.

Erosive esophagitis (healing): Oral: Initial: 20-40 mg once daily for 4-8 weeks; if incomplete healing, may continue for an additional 4-8 weeks; maintenance: 20 mg once daily .

Nonerosive reflux disease (NERD) (Canadian labeling): Initial: 20 mg once daily for 2-4 weeks; lack of symptom control after 4 weeks warrants further evaluation; maintenance (in patients with successful initial therapy): 20 mg once daily as needed

Symptomatic gastroesophageal reflux: Oral: 20 mg once daily for 4 weeks; may consider an additional 4 weeks of treatment if symptoms do not resolve.

Treatment of GERD (short-term): I.V.: 20 mg or 40 mg once daily. **Note:** Indicated only in cases where oral therapy is inappropriate or not possible; safety/efficacy ≥10 days have not been established.

***Helicobacter pylori* eradication:**

Oral:

-Manufacturer labeling: 40 mg once daily administered with amoxicillin 1000 mg *and* clarithromycin 500 mg twice daily for 10 days.

- American College of Gastroenterology guidelines (Chey, 2007):

-Nonpenicillin allergy: 40 mg once daily administered with amoxicillin 1000 mg *and* clarithromycin 500 mg twice daily for 10-14 days.

- Penicillin allergy: 40 mg once daily administered with clarithromycin 500 mg *and* metronidazole 500 mg twice daily for 10-14 days **or** 40 mg once daily administered with bismuth subsalicylate 525 mg *and* metronidazole 250 mg *plus* tetracycline 500 mg 4 times daily for 10-14 days

Canadian labeling: Esomeprazole magnesium: 20 mg twice daily for 7 days; requires combination therapy

Prevention of NSAID-induced gastric ulcers: Oral:

U.S. labeling: Esomeprazole magnesium, esomeprazole strontium: 20-40 mg once daily for up to 6 months

Canadian labeling: Esomeprazole magnesium: 20 mg once daily for up to 6 months

Note: 40 mg daily did not show additional benefit over 20 mg daily in clinical trials.

Treatment of NSAID-induced gastric ulcers: 20 mg once daily for 4-8 weeks.

Pathological hypersecretory conditions (Zollinger-Ellison syndrome): 40 mg twice daily; adjust regimen to individual patient needs; doses up to 240 mg daily have been administered.

Geriatric:
Refer to adult dosing. No dosage adjustment needed.

Renal Impairment:
Oral:

-Esomeprazole magnesium: Mild-to-severe impairment: No dosage adjustment necessary.

Esomeprazole strontium:

-Mild-to-moderate impairment: No dosage adjustment necessary.

-Severe impairment: Use is not recommended (has not been studied).

I.V.: Mild-to-severe impairment: No dosage adjustment necessary.

Hepatic Impairment:
Safety and efficacy not established in children with hepatic impairment.

-Mild-to-moderate impairment (Child-Pugh class A or B): No dosage adjustment necessary.
-Severe impairment (Child-Pugh class C): Dose should not exceed 20 mg daily.

Common side effect: Headache.

Pregnancy Risk Factor: B