PRESCRIBING INFORMATION

EZOME (esomeprazole magnesium) delayed-release capsules, for oral use

EZOME (esomeprazole magnesium) for delayed-release oral suspension Initial U.S. Approval: 1989 (omeprazole)

----------INDICATIONS AND USAGE----------

EZOME is a proton pump inhibitor indicated for the following:

• Treatment of gastroesophageal reflux disease (GERD) (1.1)

• Risk reduction of NSAID-associated gastric ulcer (1.2)

• H. pylori eradication to reduce the risk of duodenal ulcer recurrence (1.3)

• Pathological hypersecretory conditions, including Zollinger-Ellison syndrome (1.4)

----------DOSAGE AND ADMINISTRATION----------

Indication	Dose	Frequency
Gastroesophageal Reflux Disease (GERD)		
Adults	20 mg or 40 mg	Once daily for 4 to 8 weeks
12 to 17 years	20 mg or 40 mg	Once daily for up to 8 weeks
1 to 11 years	10 mg or 20 mg	Once daily for up to 8 weeks
1 month to less than 1 year: 2.5 mg, 5 mg or 10 mg (based on weight). Once daily, up to 6 weeks for erosive esophagitis (EE) due to acid-mediated GERD only.		
Risk Reduction of NSAID-Associated Gastric Ulcer		
	20 mg or 40 mg	Once daily for up to 6 months
H. pylori Eradication (Triple Therapy):		
EZOME	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		
	40 mg	Twice daily

See full prescribing information for administration options (2)

Patients with severe liver impairment-do not exceed dose of 20 mg (2)

----------DOSAGE FORMS AND STRENGTHS----------

• EZOME Delayed-Release Capsules: 20 mg and 40 mg (3)

• EZOME For Delayed-Release Oral Suspension: 2.5 mg, 5 mg, 10 mg, 20 mg, and 40 mg (3)

----------**CONTRAINDICATIONS**----------

Patients with known hypersensitivity to proton pump inhibitors (PPIs) (angioedema and anaphylaxis have occurred) (4)

----------**WARNINGS AND PRECAUTIONS**----------

• Symptomatic response does not preclude the presence of gastric malignancy (5.1)

• Atrophic gastritis has been noted with long-term omeprazole therapy. (5.2)

• Acute interstitial nephritis has been observed in patients taking PPIs. (5.3)

• Cyanocobalamin (vitamin B-12) Deficiency: Daily long-term use (e.g., longer than 3 years) may lead to malabsorption or a deficiency of cyanocobalamin. (5.4)

• PPI therapy may be associated with increased risk of Clostridium difficile associated diarrhea. (5.5)

• Avoid concomitant use of EZOME with clopidogrel. (5.6)

• Bone Fracture: Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine. (5.7)

• Hypomagnesemia has been reported rarely with prolonged treatment with PPIs. (5.8)

• Avoid concomitant use of EZOME with St John's Wort or rifampin due to the potential reduction in esomeprazole levels. (5.9, 7.3)

• Interactions with diagnostic investigations for Neuroendocrine Tumors: Increases in intragastric pH may result in hypergastrinemia and enterochromaffin-like cell hyperplasia and increased chromogranin A levels which may interfere with diagnostic investigations for neuroendocrine tumors. (5.10, 12.2)

----------**ADVERSE REACTIONS**----------

Most common adverse reactions (6.1):

• Adults (≥ 18 years) (incidence > 1%) are headache, diarrhea, nausea, flatulence, abdominal pain, constipation, and dry mouth

• Pediatric (1 to 17 years) (incidence > 2%) are headache, diarrhea, abdominal pain, nausea, and somnolence

• Pediatric (1 month to less than 1 year) (incidence 1%) are abdominal pain, regurgitation, tachypnea, and increased ALT