



**Presentation**

Esonix<sup>®</sup> 20 tablet: Each delayed release tablet contains Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg.  
 Esonix<sup>®</sup> 40 tablet: Each delayed release tablet contains Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 40 mg.  
 Esonix<sup>®</sup> 20 capsule: Each delayed release capsule contains Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg.  
 Esonix<sup>®</sup> 40 capsule: Each delayed release capsule contains Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 40 mg.  
 Esonix<sup>®</sup> 20 delayed-release oral suspension : Each sachet contains Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg.  
 Esonix<sup>®</sup> 20 IV Injection: Each vial contains sterile lyophilized powder of Esomeprazole Sodium INN equivalent to Esomeprazole 20 mg.  
 Esonix<sup>®</sup> 40 IV Injection: Each vial contains sterile lyophilized powder of Esomeprazole Sodium INN equivalent to Esomeprazole 40 mg.

**Description**

Esomeprazole (Esonix) is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H<sup>+</sup>/K<sup>+</sup>ATPase in the gastric parietal cell. By acting specifically on the proton pump, Esonix blocks the final step in acid production, thus reducing gastric acidity.

**Indications and Usage**

Treatment of Gastroesophageal Reflux Disease (GERD), Healing of Erosive Esophagitis, Maintenance of Healing of Erosive Esophagitis, Symptomatic Gastroesophageal Reflux Disease, *H. pylori* eradication to reduce the risk of Duodenal Ulcer recurrence, Zollinger-Ellison Syndrome, Acid Related Dyspepsia, Duodenal and Gastric Ulcer

**Dosage and Administration**

**Tablet/Capsule/Suspension:** The recommended adult dosages are outlined in the table below. Esonix delayed release tablet/capsule/suspension should be swallowed whole and taken at least one hour before eating.

**Recommended Dosage Schedule:**

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 Gastroesophageal Reflux Disease	20 mg	Once Daily for 4 Weeks**
<b>Pediatric GERD</b> <b>12 to 17 Year Olds:</b> Short-term Treatment of GERD <b>1 to 11 Year Olds:</b> Short-term Treatment of Symptomatic GERD <b>Healing of Erosive Esophagitis</b>	20 mg or 40 mg 10 mg	Once Daily for up to 8 Weeks Once Daily for up to 8 Weeks
weight <20 kg	10 mg	Once Daily for 8 Weeks
weight ≥20 kg	10 mg or 20 mg	Once Daily for 8 Weeks
Risk Reduction of NSAID-Associated Gastric Ulcer	20 mg or 40 mg	Once Daily for up to 6 months
<i>H. pylori</i> eradication to reduce the risk of Duodenal Ulcer recurrence <b>Triple Therapy:</b> Esomeprazole Amoxicillin Clarithromycin	40 mg 1000 mg 500 mg	Once Daily for 10 Days Twice Daily for 10 Days Twice Daily for 10 Days
Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome	40 mg	Twice Daily

\*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.

\*\*If symptoms do not resolve completely after 4 weeks, an additional 4 weeks of treatment may be considered.

**Injection**

**GERD with Erosive Esophagitis:**

**Adults:** Dose is either 20 mg or 40 mg Esomeprazole given once daily by intravenous injection (not less than 3 minutes) or intravenous infusion (10 minutes to 30 minutes).

**Pediatric:** Give the following doses once daily as an intravenous infusion over 10 minutes to 30 minutes.

**1 year to 17 years:**

Body weight less than 55 kg: 10 mg

Body weight 55 kg or greater: 20 mg

**1 month to less than 1 year of age:** 0.5 mg/kg

**Directions for reconstitution of solution**

Solution for injection is prepared by adding 5 ml of 0.9% Sodium Chloride for intravenous injection into the vial containing the dry powder. The reconstituted solution for injection is clear and colorless to very slightly yellow.

**Administration**

IV injection must be administered intravenously over a period of at least 3 minutes. Prepared solution must be used within 12 hours of preparation and can be exposed to normal indoor lighting at a maximum of 30 °C.

**Geriatric:** No dosage adjustment is necessary. **Renal Insufficiency:** No dosage adjustment is necessary. **Hepatic Insufficiency:** 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 Esonix should not be exceeded.

**Use in Pregnancy and Lactation**

**In Pregnancy:** Pregnancy Category C. This drug should be used during pregnancy only if clearly needed.

**In Lactation:** The excretion of Esomeprazole in milk has not been studied. As Esomeprazole is likely to be excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Side-effects**

In general, Esomeprazole was well tolerated in both short- and long-term clinical trials. The most frequently occurring adverse events (>1%) are headache and diarrhea, nausea, flatulence, abdominal pain, constipation and dry mouth occurred at similar rates among patients taking Esomeprazole.

**Contraindications**

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

**Precautions**

Symptomatic response to therapy with Esomeprazole does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole, of which Esomeprazole is an enantiomer.

**Drug Interactions**

Drug interaction studies have shown that Esomeprazole does not have any clinically significant interactions with Phenytoin, Warfarin, Quinidine, Clarithromycin or Amoxicillin. Esomeprazole inhibits gastric acid secretion. Therefore, Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (eg, Ketoconazole, Iron salts and Digoxin). Coadministration of oral contraceptives, Diazepam, Phenytoin or Quinidine did not seem to change the pharmacokinetic profile of Esomeprazole.

**Commercial Pack**

Esonix<sup>®</sup> 20 tablet: Each box contains 5 Alu-Alu blister strips of 14 tablets.

Esonix<sup>®</sup> 40 tablet: Each box contains 2 Alu-Alu blister strips of 14 tablets.

Esonix<sup>®</sup> 20 capsule: Each box contains 7 Alu-Alu blister strips of 8 capsules.

Esonix<sup>®</sup> 40 capsule: Each box contains 5 Alu-Alu blister strips of 6 capsules.

Esonix<sup>®</sup> 20 delayed-release oral suspension: Each box contains 30 packets.

Esonix<sup>®</sup> 20 IV Injection: Each box contains 1 vial of lyophilized Esomeprazole 20 mg, 1 ampoule of 5 ml 0.9% Sodium Chloride BP injection for intravenous injection and 1 sterile syringe (5 ml).

Esonix<sup>®</sup> 40 IV Injection: Each box contains 1 vial of lyophilized Esomeprazole 40 mg, 1 ampoule of 5 ml 0.9% Sodium Chloride BP injection for intravenous injection and 1 sterile syringe (5 ml).