

Esomenta™

Esomeprazole

Composition:

Esomenta™ 20 Capsule: Each capsule contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Esomenta™ 40 Capsule: Each capsule contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 40 mg.

Description:

Esomenta™ (Esomeprazole Magnesium Trihydrate) is the S-isomer of the proton pump inhibitor, Omeprazole. The most potent suppressors of gastric acid secretion are inhibitors of the gastric H⁺ K⁺ ATPase (proton pump). In typical doses, these drugs diminish the daily production of acid (basal & stimulated) by 80% to 95%. Esomeprazole is a prodrug with an acid-resistant enteric coating to protect them from premature activation by gastric acid. The coating is removed in the alkaline duodenum and the prodrug, a week base, is absorbed and transported to the parietal cell canaliculus. There, it is converted to the active form, which reacts with a cysteine residue of the H⁺ K⁺ ATPase, forming a stable covalent bond, thereby suppresses hydrogen ions into the gastric lumen. Thus Esomeprazole inhibits the final step in the secretion of gastric acid.

Indications:

NSAID-associated gastric ulcer
Gastro-oesophageal reflux disease
Prophylaxis in patients with an increased risk of gastroduodenal complications who require continued NSAID treatment
Zollinger-Ellison syndrome
Duodenal ulcer associated with *Helicobacter pylori*

Dosage & Administration:

NSAID-associated gastric ulcer: Adult over 18 years-20 mg once daily for 4-8 weeks.

Gastro-oesophageal reflux disease: Adult & Child over 12 years-40 mg once daily for 4 weeks, continued for further 4 weeks if not fully healed of symptoms persist. Maintenance 20 mg daily.

Symptomatic treatment in the absence of oesophagitis: 20 mg daily for up to 4 weeks, then in adult over 18 years 20 mg daily when required.

Prophylaxis in patients with an increased risk of gastroduodenal complications who require continued

NSAID treatment: 20 mg daily.

Zollinger-Ellison syndrome: Adult over 18 years-initially 40 mg twice daily, adjusted according to response, usual range 80-160 mg daily (above 80 mg in 2 divided doses). **Duodenal ulcer associated with *Helicobacter pylori*:** 20 mg twice daily plus Amoxicillin 1 mg two times daily plus Clarithromycin 500 mg or 250 mg twice daily for 2 weeks.

OR AS DIRECTED BY THE PHYSICIAN.

Side Effects:

Gastro-intestinal disturbances (including nausea, vomiting, abdominal pain, flatulence, diarrhea & constipation), headache and dizziness. Less frequently dry mouth, insomnia, drowsiness, malaise, blurred vision, rash and pruritus. Other side-effects reported rarely or very rarely include taste disturbance, liver dysfunction, peripheral oedema, hypersensitivity reactions, photosensitivity, fever, sweating, depression, interstitial nephritis & blood disorders. Dermatitis is also reported. May increase the risk of gastrointestinal infections.

Precautions:

It should be used with caution in patients with liver disease. It may mask the symptoms of gastric cancer, particular care is required in those presenting with 'alarm features', in such cases gastric malignancy should be ruled out before treatment.

Pregnancy: Caution should be taken when administered to a pregnant woman.

Lactation: Caution should be exercised when administered to a nursing woman.

Contraindications:

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

Storage Condition:

Store in a cool & dry place, protect from light. Keep out of the reach of children.

Presentation:

Esomenta™ 20 Capsule: box containing 7 x10's capsules in blister pack.

Esomenta™ 40 Capsule: box containing 3 x10's capsules in blister pack.

Manufactured by:

Julphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.