

Remmo®

Esomeprazole

Tablet

Description

Esomeprazole is the S-isomer of Omeprazole. It reduces gastric acid secretion through a specific targeted mechanism of action. It is a specific inhibitor of the acid pump in the parietal cell.

MUPS (Multiple Unit Pellet System)

The Multiple Unit Pellet System (MUPS) tablet is a kind of multiparticulate system that combines the features of both controlled release tablets and modified release capsules in one dosage form.

Advantage of MUPS Tablet over Conventional Tablet & Capsules

- MUPS tablet ensures uniform & sustained release of drug over a period of time
- Ensures both fast and sustained actions
- Offers increased bioavailability
- Protects the active drug from gastric media
- Ensures uniform emptying of micro pellets from stomach into small intestine facilitates rapid dissolution of enteric coating and drug release resulting in early T_{max} and C_{max} (peak time and peak plasma concentration)
- Offers reduced dose dumping
- Controlled absorption ensures minimal plasma concentration fluctuations
- Ensures lower risk of local irritation and toxicity.

Indication and Usage

- NSAID-associated gastric ulcer
- Prophylaxis of NSAID-associated gastric ulcer in patients with an increased risk of gastro duodenal complications who require continued NSAID treatment.
- Gastro-esophageal reflux disease (in the presence of erosive reflux esophagitis)
- Symptomatic treatment of

gastro-esophageal reflux disease (in the absence of esophagitis)

- Zollinger-Ellison syndrome
- Helicobacter pylori* eradication in combination with clarithromycin and amoxicillin or metronidazole.

Dosage and Administration

- NSAID-associated gastric ulcer
Adult: 20 mg once daily for 4-8 weeks.
- Prophylaxis of NSAID-associated gastric ulcer in patients with an increased risk of gastro duodenal complications who require continued NSAID treatment
Adult: 20 mg daily
- Gastro-esophageal reflux disease (in the presence of erosive reflux esophagitis)
Adult and Adolescent over 12 years: Initially 40 mg once daily for 4 weeks, continued for further 4 weeks if not fully healed or symptoms persist, maintenance dose is 20 mg daily.
- Symptomatic treatment of gastro-esophageal reflux disease (in the absence of esophagitis)
Adult and Adolescent over 12 years: 20 mg once daily for 4 weeks, then 20 mg daily if required.
- Zollinger-Ellison syndrome
Adult: Initially 40 mg twice daily, adjusted according to response; usual dose 80-160 mg daily, daily doses above 80mg should be given in 2 divided doses.
- Helicobacter pylori* eradication in combination with clarithromycin and amoxicillin or metronidazole.
Adult: 20 mg twice daily.

Contraindications

Patients with known hypersensitivity to any component of the formulation. It should not be

used concomitantly with Nelfinavir.

Adverse Reactions

In general, Esomeprazole is well tolerated in both short and long-term use. Common adverse effects are headache and diarrhoea. Other side effects include nausea, flatulence, abdominal pain, constipation, and dry mouth.

Use in Special Population

Pregnancy and Lactation: Clinical data on exposed pregnancies with Esomeprazole are insufficient. A moderate amount of data on pregnant women indicates no malformative or foeto/neonatal toxicity of esomeprazole. Caution should be exercised when prescribing to pregnant women.

It is not known whether esomeprazole is excreted in human breast milk. There is insufficient information on the effects of esomeprazole in newborns/infants. Esomeprazole should not be used during breast-feeding.

Renal impairment: Dose adjustment is not required in patients with impaired renal function. Due to limited experience in patients with severe renal insufficiency, such patients should be treated with caution.

Hepatic impairment: Dose adjustment is not required in patients with mild to moderate liver impairment. For patients with severe liver impairment, a maximum dose of 20 mg Esomeprazole should not be exceeded.

Overdose

There is very limited experience with deliberate overdose. The symptoms described in connection with 280 mg were gastrointestinal symptoms and weakness. Single doses of 80 mg esomeprazole were uneventful. No specific antidote is known.

Esomeprazole is extensively plasma protein bound and is therefore not readily dialyzable. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilised.

Drug Interactions

Esomeprazole is a CYP2C19 inhibitor. When starting or stopping treatment with Esomeprazole, potential interactions with medicines that are metabolized through CYP2C19 should be taken into account.

Pharmaceuticals Precautions

Keep in a dry place, below 30° C. Protect from light. Keep out of the reach of children.

Commercial Pack

Remmo® 20 Tablet: Each box containing 30 tablets in 2 x 15's Alu-Alu form wallet packs. Each MUPS (Multiple Unit Pellet System) tablet contains Esomeprazole Magnesium Trihydrate EP equivalent to Esomeprazole 20 mg.

Remmo® 40 Tablet: Each box containing 30 tablets in 2 x 15's Alu-Alu form wallet packs. Each MUPS (Multiple Unit Pellet System) tablet contains Esomeprazole Magnesium Trihydrate EP equivalent to Esomeprazole 40 mg.



Manufactured by

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