GERDO™

esomeprazole 20 mg

DESCRIPTION:

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

COMPOSITION:

Each capsule contains Esomeprazole 20 mg as Esomeprazole Magnesium USP in enteric coated pellets.

CLINICAL PHARMACOLOGY:

Pharmacodynamic Properties (Mechanism of Action): Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H^+/K^+-ATPase in gastric parietal cell. The S- and R-isomers of omeprazole are protonated and converted in the acidic compartment of the parietal cell forming the active inhibitor, the achiral sulphenamide. By acting specifically on the proton pump, Esomeprazole blocks the final step in acid production, thus reducing gastric acidity. This effect is dose-related up to a daily dose of 20 to 40 mg and leads to inhibition of gastric acid secretion.

Pharmacokinetic Properties:

After oral administration peak plasma levels (Cmax) occur at approximately 1.5 hours (Tmax). The Cmax increases proportionally when the dose is increased, and there is a three-fold increase in the area under the plasma concentration-time curve (AUC) from 20 to 40 mg. Esomeprazole is 97% bound to plasma proteins. Plasma protein binding is constant over the concentration range of 2 to 20 µmol/L. Esomeprazole is extensively metabolized in the liver by the cytochrome P450 (CYP) enzyme system. Less than 1% of parent drug is excreted in the urine. Approximately 80% of an oral dose of Esomeprazole is excreted as inactive metabolites in the urine, and the remainder is found as inactive metabolites in the feces.

INDICATIONS:

GERDO™ (Esomeprazole) is indicated in the treatment of:

- Gastroesophageal Reflux Disease (GERD)
  - Healing of Erosive Esophagitis
  - Symptomatic Gastroesophageal Reflux Disease
- Risk Reduction of NSAID-Associated Gastric Ulcer
- H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence
- Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome

DOSAGE AND ADMINISTRATION:

Table 1: Recommended Dosage Schedule of Esomeprazole

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
Pediatric GERD (12 to 17 Year Old)		
Healing of Erosive Esophagitis	20 mg or 40 mg	Once Daily for 4 to 8 Weeks
Symptomatic GERD	20 mg	Once Daily for 4 Weeks
Risk Reduction of NSAID-Associated Gastric Ulcer	20 mg or 40 mg	Once Daily for up to 6 Months
H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence		
Triple Therapy:		
Esomeprazole	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 Including Zollinger-Ellison Syndrome	40 mg	Twice Daily

SPECIAL POPULATION:

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 should not be exceeded.
Gender: No dosage adjustment is necessary.

CONTRAINDICATIONS:

Esomeprazole is contraindicated in patients with known hypersensitivity to proton pump inhibitors. Hypersensitivity reactions, e.g., angioedema and anaphylactic shock, have been reported with Esomeprazole use.

PRECAUTIONS:

Exclude the possibility of malignancy when gastric ulcer is suspected and before treatment for dyspepsia. When using in combination with antibiotic, refer to the prescribing information of the respective antibiotics.

OVERDOSAGE:

There is no experience to data with deliverate overdose. Data are limited but single dose of 80 mg 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 utilized.

USE IN PREGNANCY & LACTATION:

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Animal studies have revealed no teratogenic effects.
Lactation: The excretion of Esomeprazole in breast milk has not been studied. Esomeprazole is likely to be excreted in breast milk, a dicission is made whether to discontinue the drug in account to the importance of the drug to mother.

DRUG INTERACTIONS:

Esomeprazole is extensively metabolized in the liver by CYP2C19 and CYP3A4. In vitro and in vivo studies have shown that Esomeprazole is not likely to inhibit CYPs 1A2, 2A6, 2C9, 2D6, 2E1 and 3A4. No clinically relevant interactions with drugs metabolized by these CYP enzymes would be expected. Drug interaction studies have shown that Esomeprazole does not have any clinically significant interactions with Phenytoin, Warfarin, Quinidine, Clarithromycin or Amoxicillin.

ADVERSE EFFECTS:

The most frequently occurring adverse events reported with Esomeprazole include headache, diarrhoea, nausea, flatulence, abdominal pain, constipation and dry mouth. There are no difference in types of related adverse events seen during maintenance treatment upto 12 months compared to short term treatment.

STORAGE CONDITION:

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

COMMERCIAL PACK:

GERDO™ 20 mg Capsule: Each box contains 7 X 7 capsules in Alu- Alu blister strip.

Manufactured by:
Nuvista Pharma Limited
Tongi - Gazipur

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