

Esomeprazole Tablets 40 mg

ESOMEX-40

POM

COMPOSITION :

Each enteric coated tablet contains :

Esomeprazole Magnesium Trihydrate BP
Eq. to Esomeprazole 40 mg
Excipients Q.S.
Approved colour used

THERAPEUTIC CLASS :

Proton Pump Inhibitor

PHARMACOLOGICAL ACTION :

Esomeprazole magnesium (a substituted benzimidazole), reduces gastric acid secretion through a highly targeted mechanism of action. It is a specific inhibitor of the gastric enzyme H⁺, K⁺-ATPase (the proton pump) which is responsible for acid secretion by the parietal cells of the stomach.

Pharmacokinetics : Absorption of esomeprazole is rapid, with peak plasma levels occurring approximately 1-2 hours after dose. The absolute bioavailability is 64% after a single dose of 40mg and increases to 89% after repeated once-daily administration. Esomeprazole is 97% plasma protein bound.

Food intake both delays and decreases the absorption of esomeprazole although this has no significant influence on the effect of esomeprazole on intragastric acidity.

Esomeprazole is completely metabolised by the cytochrome P450 system (CYP). Almost 80% of an oral dose of esomeprazole is excreted as metabolites in the urine, the remainder in the faeces. Less than 1% of the parent drug is found in urine.

INDICATIONS :

Esomeprazole magnesium trihydrate tablets are indicated for treatment of conditions where a reduction of gastric acid secretion is required such as: reflux esophagitis, maintenance treatment of patients with reflux esophagitis, symptomatic gastroesophageal reflux disease (i.e. heartburn and regurgitation), and H. pylori eradication.

Esomeprazole, in combination with clarithromycin and amoxicillin, is indicated for the treatment of patients with duodenal ulcer disease associated with Helicobacter pylori infection to eradicate the H. pylori and heal ulcers. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.

CONTRAINDICATIONS :

Hypersensitivity to esomeprazole, substituted benzimidazoles or any of the components of this medication.

When used for eradication of Helicobacter pylori, the contraindications for amoxicillin and clarithromycin as found in the corresponding Product Monographs should be taken into consideration.

PRECAUTIONS & WARNINGS :

In the presence of any alarm symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melaena) and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment with Esomeprazole may alleviate symptoms and delay diagnosis.

Patients on long-term treatment should be kept under regular surveillance.

Patients on on-demand treatment should be instructed to contact their physician if their symptoms change in character. When prescribing Esomeprazole for on demand therapy, the implications for interactions with other pharmaceuticals, due to fluctuating plasma concentrations of esomeprazole should be considered.

When prescribing Esomeprazole for eradication of Helicobacter pylori possible drug interactions for all components in the triple therapy should be considered. Clarithromycin is a potent inhibitor of CYP3A4 and hence contraindications and interactions for clarithromycin should be considered when the triple therapy is used in patients concurrently taking other drugs metabolised via CYP3A4 such as cisapride.

ADVERSE EFFECTS :

Central and peripheral nervous system : Common: Headache Uncommon: Dizziness

Gastrointestinal : Common: Abdominal pain, diarrhoea, flatulence, nausea/vomiting, constipation. Uncommon: Dry mouth

Skin : Uncommon: Dermatitis, pruritus, urticaria

Rarely : blurred vision, hypersensitivity reactions e.g. angioedema, anaphylactic reaction/shock, increased liver enzymes

and of myalgia.

Very rarely : Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, alopecia, and hepatitis with or without jaundice have been reported.

DOSAGE & ADMINISTRATION :

The tablets should be swallowed whole with liquid. They should not be chewed or crushed.

Gastroesophageal Reflux Disease (GERD)

Treatment of erosive reflux esophagitis 40 mg once daily for 4 weeks.

An additional 4 weeks treatment is recommended for patients in whom esophagitis has not healed or who have persistent symptoms.

Long-term management of patients with healed esophagitis to prevent relapse 20 mg once daily.

Symptomatic treatment of gastroesophageal reflux disease (GERD) 20 mg once daily in patients without esophagitis. If symptom control has not been achieved after 4 weeks, the patient should be further investigated. Once symptoms have resolved, subsequent symptom control can be achieved using an on demand regimen taking 20 mg once daily, when needed.

Patients requiring continued NSAID therapy.

Treatment of upper gastrointestinal symptoms associated with NSAID therapy 20 mg once daily in patients requiring NSAID therapy. If symptom control has not been achieved after 4 weeks, the patient should be further investigated.

Healing of gastric ulcers associated with NSAID therapy: 20 mg or 40 mg once daily for 4 to 8 weeks.

Prevention of gastric and duodenal ulcers associated with NSAID therapy in patients at risk: 20 mg or 40 mg once daily.

In combination with an appropriate antibacterial therapeutic regimen for the eradication of *Helicobacter pylori* and healing of *Helicobacter pylori* associated duodenal ulcer and prevention of relapse of peptic ulcers in patients with *Helicobacter pylori* associated ulcers 20 mg Esomeprazole with 1 g amoxicillin and 500 mg clarithromycin, all twice daily for 7 days.

Children : Esomeprazole should not be used in children since no data is available.

Impaired renal function : 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.

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

Elderly : Dose adjustment is not required in the elderly.

OVERDOSAGE :

Symptoms of overdose may include: confusion, drowsiness, blurred vision, fast heartbeat, nausea, sweating, flushing, headache, dry mouth.

Treatment should be symptomatic and supportive.

DRUG INTERACTIONS :

Diazepam or similar sedating drugs.

Certain other drugs require the presence of stomach acid to be effective. Since esomeprazole eliminates stomach acid so effectively, the absorption of the following drugs may be adversely affected: ampicillin, digoxin , iron preparations, ketoconazole.

If you take any of the above medications, ask your physician. It is okay to take antacids.

PRESENTATION :

Strip Pack / Blister Pack

STORAGE CONDITION :

Store below 30°C. Protect from light & moisture.

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