Maxpro®

(Esomeprazole Magnesium USP)

Composition:

Maxpro® tablet 20mg: Each enteric coated tablet contains Esomeprazole 20mg as Esomeprazole Magnesium Trihydrate USP.

Maxpro® tablet 40mg: Each enteric coated tablet contains Esomeprazole 40mg as Esomeprazole Magnesium Trihydrate USP.

Maxpro® capsule 20mg: Each capsule contains Esomeprazole 20mg as Esomeprazole Magnesium Trihydrate USP in enteric coated pellets.

Maxpro® capsule 40mg: Each capsule contains Esomeprazole 40mg as Esomeprazole Magnesium Trihydrate USP in enteric coated pellets.

Pharmacological action:

Esomeprazole, the S-isomer of Omeprazole, reduces gastric acid secretion through specific inhibition of the acid pump in the parietal cell, where it is concentrated and converted to the active form in the acid environment of the secretary canaliculi and inhibits the enzyme H^+K^+ATPase -the acid pump. This effect on the final step of the gastric acid secretion is dose-dependent and provides for effective inhibition of both basal and stimulated acid secretion. Food intake had no significant influence on the effect of Esomeprazole on intragastric acidity.

Indications:

The FDA approved Esomeprazole for maintenance of healing of erosive esophagitis and in combination with Amoxicillin and Clarithromycin, for the eradication of *Helicobacter pylori* infection in patients with duodenal ulcer disease. The FDA approved Esomeprazole for risk reduction of NSAID induced stomach ulcer.

Maxpro® tablets/capsules are indicated for:

Gastroesophageal Reflux Disease (GERD):

- treatment of erosive reflux esophagitis
- long-term management of patients with healed esophagitis to prevent relapse
- symptomatic treatment of gastroesophageal reflux disease (GERD)

In combination with appropriate antibacterial therapeutic regimens for the eradication of *Helicobacter pylori*:

- healing of *Helicobacter pylori* associates duodenal ulcer
- prevention of relapse of peptic ulcers in patient with *Helicobacter pylori* associated ulcer disease

Dosage and directions for use:

The tablets should be swallowed whole with liquid. The tablets should not be chewed or crushed and should be taken one hour before eating.

Indication	Dose	Frequency
Gastroesophageal Reflux Disease (GERD)		
Healing of Erosive Esophagitis	20mg or 40mg	Once daily for 4 to 8 weeks*
Maintenance of Healing of Erosive Esophagitis	20mg	Once Daily**
Symptomatic Gastroesophageal Reflux	20mg	Once daily for 4 weeks***
Triple Therapy for *H. pylori* Eradication		
Maxpro®	20mg	Twice daily for 7 days
Amoxycillin	1000mg	Twice daily for 7 days
Clarithromycin	500mg	Twice daily for 7 days

* 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 treatment may be considered.** Controlled studies did not extend beyond six months.

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

Size: 120 x 240mm

Children:
FDA approved Esomeprazole for children aged 1-11 years. Dose: <20kg body weight 5 to 10mg/day and >20kg body weight 10 to 20mg/day.

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 dose of Maxpro® should be used.

Elderly:
Dose adjustment is not required in the elderly.

Side-effects and special precautions:
The following adverse drug reactions have identified or suspected in the clinical trials programme for Esomeprazole. More frequent: Headache, abdominal pain, diarrhoea , flatulence, nausea/ vomiting and Less frequent: Dermatitis, pruritus, urticaria, dizziness.

Contra-indications:
Known hypersensitivity to Esomeprazole, substituted Benzimidazoles or any other constituents of the formulation.

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 (particularly those treated for more than a year), should be kept under regular surveillance.

Drug Interactions:
In common with the use of other inhibitors of acid secretion or antacids, the absorption of Ketoconazole and Itraconazole can decrease during treatment with Esomeprazole. When Esomeprazole is combined with drugs ,such as Diazepam, Citalopram, Imipramine, Clomipramine, Phenytoin etc ,the plasma concentrations of these drugs may be increased and a dose reduction could be needed . Concomitant administration of 30mg Esomeprazole resulted in a 45% decrease in clearance of the CYP2C19 substrate Diazepam. Concomitant administration of 40mg Esomeprazole resulted in a 13% increase in trough plasma levels of phenytoin in epileptic patients. It is recommended to monitor the plasma concentrations of phenytoin when treatment with Esomeprazole is introduced or withdrawn.

Pregnancy and lactation:
FDA pregnancy category B. No fetal teratogenicity or harm. Limited human pregnancy data. Use is acceptable for aspiration prophylaxis during pregnancy.

Effects on the ability to drive and use machines:
No effects have been observed.

Known symptoms of over dosage and particulars of its treatment:
The symptoms described in connection with deliberate Esomeprazole overdose are transient. The symptoms described in connection with 280mg were gastrointestinal symptoms and weakness. Single doses of 80mg Esomeprazole were uneventful. No specific antidote is known. Esomeprazole is extensively 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.

Pharmaceutical precaution :
Store in a cool and dry place, protected from light. Keep out of the reach of children.

How Supplied :

Maxpro® tablet 20mg	: Box containing 5 x 10's / 7 x 10's / 10 x 10's / 9 x 14's / 10 x14's tablets in Alu-Alu blister pack.
Maxpro® tablet 40mg	: Box containing 3 x 10's / 4 x 10's / 5 x 10's / 6 x 10's tablets in Alu-Alu blister pack.
Maxpro® capsule 20mg	: Box containing 10 x 6's / 16 x 6's / 10 x 10's capsules in Alu-Alu blister pack, 30 / 60 capsules in plastic container.
Maxpro® capsule 40mg	: Box containing 5 x 6's / 10 x 6's / 10 x 10's capsules in Alu-Alu blister pack, 30 / 60 capsules in plastic container.

® Trade Mark

Manufactured by
Renata Limited
Mirpur, Dhaka, Bangladesh
Tablet & Capsule (20mg & 40mg)

Manufactured by
Renata Limited
Rajendrapur, Gazipur, Bangladesh.
Tablet & Capsule (20mg & 40mg)

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