Rapo-20
Rabeprazole

COMPOSITION
Rapo-20 mg Tablet: Each enteric-coated tablet contains Rabeprazole Sodium INN 20 mg.

PHARMACOLOGY
Rabeprazole suppresses gastric acid secretion by inhibiting the gastric
H+/K+-ATPase at the secretory surface of the gastric parietal cell. It blocks the final step of gastric acid secretion.

PHARMACOKINETICS
Following oral administration of 20 mg, Rabeprazole is absorbed and can be detected in plasma by 1 hour. The effects of food on the absorption of Rabeprazole have not been evaluated. Rabeprazole is 96.3% bound to human plasma proteins. Rabeprazole is primarily metabolized in the liver by cytochromes P450 3A (sulphone metabolite) and 2C19 (desmethyl- Rabeprazole). Following a single 20 mg oral dose of 14C-labeled Rabeprazole, approximately 90% of the drug is eliminated in the urine. The remainder of the dose is recovered in the faeces.

INDICATIONS
Healing of erosive or ulcerative gastro-esophageal reflux disease; Maintenance of healing of erosive or ulcerative gastro-esophageal reflux disease; Benign gastric ulcer; Healing of duodenal ulcer; Treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome.

DOSAGE & ADMINISTRATION
Healing of erosive or ulcerative gastro-esophageal reflux disease (GERD): 20 mg once daily in the morning for 4-8 weeks. For those patients who have not been healed after 8 weeks of treatment, an additional 8-week course may be considered.
Maintenance of healing of erosive or ulcerative gastroesophageal reflux disease: 20 mg once daily in the morning.
Benign gastric ulcer: 20 mg once daily in the morning for 6 weeks, followed by a further 6 weeks if not fully healed.
Healing of duodenal ulcer: 20 mg once daily in the morning for a period upto 4 weeks. A few patients may require additional therapy to achieve healing. Pathological hypersecretory conditions including Zollinger-Ellison Syndrome: The recommended adult oral starting dose is 60 mg daily. Doses should be adjusted to individual patient needs and should be continued as long as clinically indicated. Some patients may require divided doses.

SIDE EFFECTS
Dry mouth, gastrointestinal disturbances (including diarrhoea, nausea and vomiting, constipation, flatulence, abdominal pain), liver dysfunction, taste disturbance, hypersensitivity reactions (including rash, urticaria, angioedema, bronchospasm, anaphylaxis), peripheral oedema, depression, dizziness, drowsiness, headache, insomnia, fever, haematological changes (including agranulocytosis, leucocytosis, leucopenia, pancytopenia, thrombocytopenia), interstitial nephritis, muscle and joint pain, blurred vision, photosensitivity, pruritus, severe skin reactions (including Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous eruption), sweating, malaise. Proton pump inhibitors decrease gastric acidity and may increase the risk of gastro-intestinal infections, cough, pharyngitis, rhinitis, asthenia, influenza-like syndrome; less commonly chest pain, sinusitis, nervousness, rarely stomatitis, encephalopathy in severe liver disease, anorexia, weight gain.

USE IN PREGNANCY & LACTATION
There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. A decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother. The safety and effectiveness of Rabeprazole in paediatric patients have not been established.

CONTRAINDICATIONS
Known hypersensitivity to Rabeprazole, substituted benzimidazoles or any component of the formulation.

PRECAUTIONS
Administration of Rabeprazole to patients with mild to moderate liver impairment resulted in increased exposure and decreased elimination. Caution should be exercised in patients with severe hepatic impairment.

DRUG INTERACTIONS
Rabeprazole is metabolized by the cytochrome P450 (CYP450) drug metabolizing enzyme system. Rabeprazole does not have clinically significant interactions with other drugs metabolized by the CYP450 system, such as warfarin and theophylline given as single oral dose, diazepam as a single intravenous dose, and phenytoin given as a single intravenous dose. In normal subjects, co-administration of Rabeprazole 20 mg QD resulted in an approximately 30% decrease in the bioavailability of ketoconazole and increase in the AUC and Cmax for digoxin of 90% and 29% respectively.

OVERDOSAGE
There has been no experience with large overdoses with Rabeprazole. No specific antidote for Rabeprazole is known. Rabeprazole is extensively protein bound and is not readily dialyzable. In the event of over dosage, treatment should be symptomatic and supportive.

PHARMACEUTICAL PRECAUTIONS
Store in a cool and dry place, protected from light.

HOW SUPPLIED
Rapo-20 Tablet: Each carton contains 5 sachets. Each sachet contains 1 blister strip of 10 tablets.

Manufactured by

MEDICON **MEDICON** Pharmaceuticals Ltd
Mirpur, Dhaka, Bangladesh