RABLET 20

Rabeprazole Sodium BP
20 mg Tablet

COMPOSITION
Each enteric coated tablet contains Rabeprazole Sodium Hydrate BP equivalent to Rabeprazole Sodium BP 20 mg.

PHARMACOLOGY
Rabeprazole Sodium suppresses gastric acid secretion by inhibiting the gastric H^+/K^+-ATPase at the secretory surface of the gastric parietal cell. Because this enzyme is regarded as the acid (proton) pump within the parietal cell, Rabeprazole has been characterized as a gastric proton-pump inhibitor.

INDICATION
Rablet 20 is indicated in Duodenal ulcer, Healing of erosive or ulcerative Gastroesophageal Reflux Disease (GERD), Treatment of symptomatic GERD, Maintenance of healing of erosive or ulcerative GERD, Zollinger-Ellison Syndrome, Helicobacter pylori eradication to reduce the risk of Duodenal Ulcer recurrence.

DOSAGE AND ADMINISTRATION
1) Duodenal ulcer: 20 mg once daily in the morning for 4 weeks. Most patients heal within 4 weeks.

2) Healing of erosive or ulcerative Gastroesophageal Reflux Disease (GERD): 20 mg once daily for 4 to 8 weeks. Those patients who have not healed after 8 weeks of treatment, an additional 8-week course of treatment may be considered.

3) Treatment of symptomatic GERD: The recommended adult oral dose is 20 mg once daily for 4 weeks. If symptoms do not resolve completely after 4 weeks, an additional course of treatment may be considered.

4) Maintenance of healing of erosive or ulcerative GERD: The recommended adult oral dose is 20 mg once daily. Controlled studies do not extend beyond 12 months.

5) Zollinger-Ellison Syndrome: The recommended adult oral starting dose is 60 mg once a day. Doses should be adjusted according to individual patient needs and should continue for as long as clinically indicated. Some patients may require divided doses. Doses up to 100 mg once daily and 60 mg twice daily have been administered.

***6) Helicobacter pylori* eradication to reduce the risk of Duodenal Ulcer recurrence:**

Rabeprazole Sodium	20 mg	Twice daily in the morning and evening with meals for 7 days
Amoxicillin	1000 mg	
Clarithromycin	500 mg	

CONTRAINDICATION
Rabeprazole Sodium is contraindicated in patients with known hypersensitivity to Rabeprazole Sodium, other PPIs or to any component of the formulation.

WARNING AND PRECAUTION
Rabeprazole Sodium tablets should not be splitted, chewed or crushed.

SIDE EFFECT
In general, Rabeprazole Sodium is well-tolerated in both short-term and long-term studies. Rabeprazole Sodium may sometimes cause headache, diarrhoea, abdominal pain, vomiting, constipation, dry mouth, increased or decreased appetite, muscle pain, drowsiness, dizziness.

USE IN PREGNANCY & LACTATION
Studies have been performed in animals and have revealed no evidence of impaired fertility or harm to the fetus due to Rabeprazole Sodium. There are however, no adequate and well-controlled studies in pregnant women. Rabeprazole Sodium is likely to be excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

USE IN CHILDREN & ADOLESCENTS
The safety and effectiveness of Rabeprazole Sodium 20 mg in paediatric patients less than 12 years have not been established.

DRUG INTERACTION
Studies in healthy subjects have shown that Rabeprazole Sodium does not have clinically significant interactions with other drugs metabolized by the CYP-450 system, such as Warfarin and Theophylline given as single oral doses, Diazepam as a single intravenous dose, and Phenytoin given as a single intravenous dose.

OVERDOSE
There is no experience with large overdoses with Rabeprazole Sodium. The maximum reported overdose is 80 mg. There are no clinical signs or symptoms associated with any reported overdose. Patients with Zollinger-Ellison syndrome have been treated with up to 120 mg Rabeprazole Sodium once daily. No specific antidote for Rabeprazole Sodium is known.

STORAGE
Keep below 30°C temperature, away from light & moisture. Keep out of the reach of children.

PACKING
Each box contains 50 tablets in Alu-Alu blister pack in Alu-Alu sachet.

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.