XOREL

RABEPRAZOLE USP

Compositions:
Xorel-20 Tablet: Each enteric coated tablet contains Rabeprazole Sodium USP 20 mg. Xorel-20 Capsule: Each capsule contains Rabeprazole Sodium USP 20 mg in enteric coated pellets. Xorel-10 Tablet: Each enteric coated tablet contains Rabeprazole Sodium USP 10 mg. Xorel-10 Capsule: Each sprinkle capsule contains Rabeprazole Sodium USP 10 mg.

Pharmacology:
Rabeprazole sodium, a rapid acting proton pump inhibitor (PPI). It suppresses gastric acid secretion by inhibiting the gastric H+/K+ ATPase at the secretory surface of the gastric parietal cell. This enzyme is regarded as the acid (Proton) pump within the parietal cell. Rabeprazole blocks the final step of gastric acid secretion. Because of its enteric coated formulation Xorel (Rabeprazole) is highly stable in stomach and higher pka value of Rabeprazole provides faster action compared to other PPIs.Rabeprazole sodium, a rapid acting proton pump inhibitor (PPI). It suppresses gastric acid secretion by inhibiting the gastric H+/K+ ATPase at the secretory surface of the gastric parietal cell. This enzyme is regarded as the acid (Proton) pump within the parietal cell. Rabeprazole blocks the final step of gastric acid secretion. Because of its enteric coated formulation Xorel (Rabeprazole) is highly stable in stomach and higher pka value of Rabeprazole provides faster action compared to other PPIs.

Dosage And Administration:
Xorel-20 should be swallowed whole. Xorel-20 can be taken with or without food. Healing of Erosive or Ulcerative GERD: The recommended adult oral dose is Xorel-20 to be taken once daily for 4 to 8 weeks. For those patients who have not healed after 8 weeks of treatment, an additional 8-week, course of Xorel-20 may be considered. Maintenance of Healing of Erosive or Ulcerative GERD: The recommended adult oral dose is one Xorel-20 once daily. Treatment of Symptomatic GERD: The recommended adult oral dose is one Xorel-20 once daily for 4 weeks. If symptoms do not resolve completely after 4 weeks, an additional course of treatment may be considered. Healing of Duodenal Ulcers: The recommended adult oral dose is one Xorel-20 once daily after the morning meal for a period upto 4 weeks. Most patients with duodenal ulcer heal within 4 weeks. A few patients may require additional therapy to achieve healing.Treatment of Pathological Hypersecretory Conditions, Including Zollinger-Ellison Syndrome: The dosage of Rabeprazole in patients with pathological hypersecretory conditions varies with the individual patient. The recommended adult oral starting dose is 60 mg once a day. Doses should be adjusted to individual patients needs and should continue for as long as clinically indicated. Some patients may require divided doses. Some patients with Zollinger-Ellison syndrome have been treatedcontinuously with Xorel-20 for up to one year. Treatment of GERD in Pediatric Patients 1 to 11 Years of Age: The recommended dosage for pediatric patients 1 to 11 years of age by body weight is:Xorel-20 20 mg Amoxicillin, Clarithromycin 1000 mg 500 mg twice daily with the morning and evening meals for 7 days 1. Less than 15 kg: 5 mg once daily for up to 12 weeks with the option to increase to 10 mg if inadequate response. 2. 15 kg or more: 10 mg once daily for up to 12 weeks.

Contraindications:
Rabeprazole is contraindicated in patients with known hypersensitivity to Rabeprazole or to any component of the formulation.

Warning And Precaution:
Administration of Rabeprazole to patients with mild to moderate liver impairment results in increased exposure and decreased elimination. Caution should be exercised in patients with severe hepatic impairment.

Side Effects:
Rabeprazole are generally well tolerated. The observed undesirable effects have been generally mild/moderate and transient in nature. The most common adverse events are headache, diarrhea and nausea. The less common adverse effects are abdominal pain, asthenia, flatulence, rash, dry mouth etc.

Use in Pregnancy and Lactation:
Use in pregnancy & Lactation: Pregnancy category B. There are no adequate well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Use in Nursing Mother: Since many drugs are excreted in milk, and because of the potential for adverse reactions to nursing infants from Rabeprazole, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Drug Interaction:
Rabeprazole like other PPIs is metabolized through Cytochrome P450 drug metabolizing enzyme system. But Rabeprazole does not have clinically significant interaction with other drugs metabolized by CYP P450 system, such as Warfarin, Theophylline, Diazepam and Phenytoin. Rabeprazole inhibits gastric acid secretion and may interfere with absorption of drugs where gastric pH is an important determinant of bioavailability e.g. Ketoconazole, Iron salts and Digoxin. In studies no interaction with liquid antacid or foods was observed.

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

Storage:
Keep in a cool (below 30°C) and dry place, protected from light. Keep out of the reach of children.

Packing:
Xorel-20 Tablet: Each box contains 10X10 tablets in Alu-Alu blister pack. Xorel-20 Capsule: Each box contains 10X10 capsules in Alu-Alu blister pack. Xorel-10 Tablet: Each box contains 10X10 tablets in Alu-Alu blister pack. Xorel-10 Capsule: Each box contains 10X10 capsules in Alu-Alu blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
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