

XOREL MUPS

RABEPRAZOLE USP

Compositions:

Xorel MUPS 20 Tablet: Each MUPS (Multiple Unit Pellet System) tablet contains Rabeprazole Sodium enteric coated pellets Pharma Grade equivalent to Rabeprazole Sodium BP 20 mg. MUPS: Multiple Unit Pellet System is known as MUPS. The tablets are prepared by compaction of modified release coated pellets along with cushioning granules. MUPS is the latest technology which combines the power of both tablets and pellet filled capsules in one single dosage form.

Pharmacology:

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. Besides, Rabeprazole sodium stimulates gastric mucin production (main component of gastric mucus which gives protection to stomach against gastric acid). Clinical Advantage of Xorel MUPS Tablet: 1.Ensures greater bioavailability 2. Ensures uniform drug release 3. Once daily dose 4. Ensures less possibility of dose dumping 5. Ensures lesser chance of localized irritation. 6. Ensures uniform emptying of micro pellets from stomach into small intestine. Pharmacodynamic Advantages: MUPS tablet ensures rapid and uniform gastric emptying and subsequently uniform drug dissolution of pellets in the gastrointestinal tract due to their small size and larger surface, uniform drug absorption is facilitated which results in consistent and controlled pharmacological action.

Dosage And Administration:

Disease Dosage Frequency Risk reduction of NSAID induced Gastric Ulcer 20 mg Once daily for 4-8 weeks Treatment of active Duodenal Ulcer 20 mg Once daily for 4-8 weeks Benign Gastric Ulcer 40 mg Once daily for 4 to 8 weeks Treatment of symptomatic GERD 20 mg Once daily for 4 weeks Treatment of symptomatic GERD in adolescents (12 years & above) 20 mg Once daily for 4-8 weeks Treatment of symptomatic GERD in 1 to 11 years old <15 kg body weight; 5 mg with the option to increase to 10 mg if inadequate response. ≥15 kg body weight; 10 mg Once daily for 12 weeks Zollinger-Ellison Syndrome 40-80 mg & Helicobacter pylori Eradication 20 mg with Amoxicillin 1000 mg & Clarithromycin 500 mg together Twice daily as long as per physician prescription & Method of taking Xorel MUPS Tablet: Shallow the MUPS tablet with a glass of water. The tablet should not be chewed or crushed. & If patients have trouble to swallow the whole tablet, put the tablet into a glass of drinking water then stir until the tablet disintegrate and then drink the liquid mixture within 30 minutes. Stir the mixture just as always before drinking. & Xorel MUPS Tablet can shallow before or after meal.

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 most common adverse events are headache, abdominal pain, diarrhea, rash, dry mouth and nausea etc.

Use in Pregnancy and Lactation:

Pregnancy category B. 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:

Possible interaction with Warfarin, cyclosporine, ketoconazole, Iron salts, digoxin, Mycophenolatemofetil, Atazanavir, methotrexate.

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:

Store in a cool (below 30°C) and dry place, protect from light. Keep out of reach of children.

Packing:

Xorel MUPS 20 Tablet: Each box contains 5x10 MUPS tablets in Alu-Alu blister pack.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.