RABZ

COMPOSITION:

RABZ 20mg Tablets
Each delayed release tablet contains:
Rabeprazole Sodium (M.S.) ..... 20 mg
Product Conforms to the Manufacturer's Specifications.

RABZ 20mg Injection
Each vial contains:
Rabeprazole Sodium (M.S.) ..... 20 mg
As sterile freeze-dried powder for reconstitution with 5 ml of sterile water for injection
Product Conforms to the Manufacturer's Specifications.

DESCRIPTION:

The active ingredient contained in
RABZ is Rabeprazole Sodium which is a substituted benzimidazole that inhibits gastric acid secretion.

PHARMACODYNAMICS:

Mechanism of Action:
Rabeprazole Sodium belongs to a class of anti-secretory compound (substituted benzimidazole proton-pump inhibitors) that suppress 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 Sodium has been characterized as a gastric proton-pump inhibitor. Rabeprazole Sodium blocks the final step of gastric acid secretion. In gastric parietal cells Rabeprazole Sodium is protonated, accumulates and is transformed to an active Sulfonamide.

Anti-secretory Activity:
The anti-secretory effect begins within one hour after oral administration of 20 mg Rabeprazole Sodium (RABZ). In patients with gastroesophageal reflux disease (GERD) and moderate to severe esophageal acid exposure, Rabeprazole Sodium (RABZ) 20 mg and 40 mg per day decreases 24 hour esophageal acid exposure.

PHARMACOKINETICS:

RABZ tablets are enteric coated to allow Rabeprazole Sodium, which is acid labile, to pass through the stomach relatively intact. After oral administration of 20 mg Rabeprazole Sodium (RABZ), peak plasma concentrations (Cmax) of Rabeprazole Sodium occur over a range of 2.0 to 5.0 hours (T max). The Rabeprazole Sodium Cmax and AUC are linear over an oral dose range of 10 mg to 40 mg. There is no appreciable accumulation when doses of 10 mg to 40 mg are administered every 24 hours; the pharmacokinetics of Rabeprazole Sodium are not altered by multiple dosing. The plasma half-life ranges from 1 to 2 hours.

RABZ

Absorption of Tablet:
Absolute bioavailability for a 20 mg oral tablet of Rabeprazole Sodium (RABZ) compared to intravenous administration is approximately 52%. The effects of food on the absorption of Rabeprazole Sodium have not been evaluated.

Absorption of Injection:
Absolute bioavailability of Rabeprazole Sodium I.V. is 100%. Rabeprazole Sodium is 96.3% bound to human plasma proteins.

Distribution:
Rabeprazole Sodium is 96.3% bound to human plasma proteins.

Metabolism:
Rabeprazole Sodium is extensively metabolized. Thioether and Sulphone are the primary metabolites measured in human plasma. These metabolites were not observed to have significant anti-secretory activity. In vitro studies have demonstrated that Rabeprazole Sodium is metabolized in the liver primarily by cytochrome P450 3A (CYP3A) to a Sulphone metabolite and cytochrome P450 2C19 (CYP2C19) to Desmethyl Rabeprazole. The thioether metabolite is formed non-enzymatically by reduction of Rabeprazole.

Elimination:
Following a single 20 mg oral dose of Rabeprazole Sodium, approximately 90% of the drug was eliminated in the urine, primarily as thioether carboxylic acid, its glucoronide and mercapturic acid metabolites. The remainder of the dose was recovered in the feces. No unchanged Rabeprazole was recovered in the urine or feces.

INDICATIONS OF TABLET:

Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD):
Rabeprazole Sodium (RABZ) is indicated for short-term (4 to 8 weeks) treatment in the healing and symptomatic relief of erosive or ulcerative gastroesophageal reflux disease (GERD). For those patients who have not healed after 8 weeks of treatment, an additional 8 week course of Rabeprazole Sodium (RABZ) may be considered. Rabeprazole Sodium (RABZ) is indicated for maintaining healing and reduction in relapse rates of heartburn symptoms in patients with erosive or ulcerative gastroesophageal reflux disease (GERD maintenance).

Duodenal Ulcers:
Rabeprazole Sodium (RABZ) is indicated for short-term (up to 4 weeks) treatment in the healing and symptomatic relief of duodenal ulcers. Mostly patients heal within 4 weeks.

Pathological Hypersecretory Conditions, Including Zollinger-Ellison Syndrome:
Rabeprazole Sodium (RABZ) is indicated for the long-term treatment of pathological hypersecretory conditions including Zollinger-Ellison syndrome.

RABZ

INDICATIONS OF INJECTION:

The intravenous administration is recommended only in cases where the oral administration is not indicated. As soon as an oral therapy
is possible the intravenous therapy should be discontinued. Recommended dose is intravenous administration of the content of one vial
(20mg Rabeprazole) once daily. Parenteral routes of administration other than intravenous are not recommended.
Injection: The content of the vial needs to be reconstituted with 5 ml sterile water for injection, which should be given slowly over 5 -15 min.
Infusion: For intravenous infusion the reconstituted solution should be further diluted and administered as short term infusion over 15-30 min.
Compatibility with various I.V. fluids: Rabeprazole I.V. is compatible with sterile water for injection and 0.9% Sodium Chloride injection.
No other solvent or infusion fluid must be used for administration of Rabeprazole I.V. injection.
Reconstitution
To reconstitute add 5 ml of sterile water for injection to make a solution. After preparation, the reconstituted solution must be used within 4
hours and the unused portion discarded. As with all parenteral admixtures, the reconstituted or further diluted solution should be examined for
change in colour, precipitation, haziness or leakage .The unused portion should be discarded.
pH of the reconstituted solution : Between 11.2-12.5.
Caution
No other solvents / drug for I.V. injection should be used simultaneously in same infusion.
NOTE: The reconstituted and diluted solutions should not be used if it contains visible particulate matter.

CONTRAINDICATIONS:

Rabeprazole Sodium (RABZ) is contraindicated in patients with known hypersensitivity to Rabeprazole, substituted Benzimidazoles or to any component of the formulation.

DRUG-DRUG INTERACTIONS:

Rabeprazole Sodium (RABZ) is metabolized by the cytochrome P450 (CYP450) drug metabolizing enzyme system. Studies in healthy subjects have shown that Rabeprazole Sodium (RABZ) does not have clinically significant interactions with other drugs metabolized by the CYP450 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. However, it may inhibit metabolism of Cyclosporin. Rabeprazole produces sustained inhibition of gastric acid secretion. An interaction with compounds which are dependent on gastric pH for absorption, may occur due to the magnitude of acid suppression observed with Rabeprazole Sodium (RABZ). Coadministration of Rabeprazole Sodium (RABZ) with Ketoconazole may decrease the bioavailability of Ketoconazole. Coadministration with Digoxin may lead to increased AUC and Cmax values for Digoxin. Therefore, patients may need to be monitored when such drugs are taken concomitantly with Rabeprazole Sodium. Coadministration of Rabeprazole Sodium (RABZ) and antacids produced no clinically relevant changes in plasma Rabeprazole Sodium (RABZ) concentrations.

RABZ

OVERDOSAGE:

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

STORAGE:

Store in a cool & dry place below 25^{O}C.
Protect from light, heat and moisture.
Keep out of reach of children.

PRESENTATION:

RABZ 20 mg Tablets are available in a blister pack of 14's.
RABZ 20mg Injection is available in a vial of 10 ml with 5 ml sterile water for injection.

Wilshire
Sign of Health & Care