

RABEPRAZOLE SODIUM

Rx

BAROLE

20mg Lyophilized Powder for I.V. Injection
Proton Pump Inhibitor

FORMULATION:

Each vial contains:
Rabeprazole sodium20 mg

PHARMACOLOGY:

Rabeprazole belongs to a class of antisecretory compounds (substituted benzimidazole proton-pump inhibitors) that do not exhibit anticholinergic or histamine H₂-receptor antagonist properties, but 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 with the parietal cell, Rabeprazole has been characterized as a gastric proton pump inhibitor. Rabeprazole blocks the final step of gastric acid secretion. In gastric parietal cells, Rabeprazole is protonated, accumulates and is transformed to an active sulfonamide.

PHARMACOKINETICS:

There is no appreciable accumulation when 10 to 40 mg dose is administered every 24 hours. The pharmacokinetic of Rabeprazole is not altered by multiple dosing. The plasma $\frac{1}{2}$ life ranges from 1 to 2 hours. Absolute bioavailability for a 20 mg oral Rabeprazole compared to intravenous is about 52%. Rabeprazole is 96.3 % bound to plasma proteins. Rabeprazole is extensively metabolized. These metabolites do not have antisecretory activity. Approximately 90% of the drug is eliminated in the urine, primarily as thioether carboxylic acid; its glucuronide, and mercapturic acid metabolites. These metabolites were not observed to have significant anti-secretory activity. No unchanged Rabeprazole is recovered in the urine or feces.

INDICATIONS:

For the treatment of severe gastroesophageal reflux disease, peptic ulcer disease and the Zollinger-Ellison syndrome.

DOSE AND ADMINISTRATION:

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 (20 mg 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 sodium (Barole) Injection is compatible with Dextrose injection, Dextrose saline injection.

Dosage in Special Populations: No dosage adjustment is necessary in elderly patients, in patients with renal disease or in patients with mild to moderate hepatic impairment. Administration of Rabeprazole to patients with mild to moderate liver impairment results in increased exposure and decreased elimination. Due to the lack of clinical data on Rabeprazole in patients with severe hepatic impairment, caution should be exercised in these patients.

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 if stored at room temperature and within 24 hours if stored in refrigerator and the unused portion should be 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

CONTRAINDICATIONS:

Rabeprazole is contraindicated in patients with known hypersensitivity to Rabeprazole, substituted benzimidazoles or to any component of the formulation.

SPECIAL WARNINGS AND PRECAUTIONS:

It is an alternative in patients in whom oral administration of Rabeprazole is not indicated. Symptomatic response to therapy with Rabeprazole does not preclude the presence of gastric malignancy.

In case of discoloration of content, please do not use and discard the vial.

DRUG INTERACTIONS:

Rabeprazole sodium undergoes an almost complete, mainly non-enzymatic, metabolism with renal elimination of the metabolites, CYP 450 enzymes contributed to the fraction of metabolism, mediated enzymatically. Rabeprazole does not have clinically significant interactions with other drugs metabolized by the CYP 450 system such as warfarin, theophylline, diazepam and phenytoin.

PREGNANCY:

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

LACTATION:

Since many drugs are excreted in milk, caution should be exercised when Rabeprazole is administered to a nursing mother.

PEDIATRIC USE:

The safety and effectiveness of Rabeprazole in pediatric patients has not been established.

GERIATRIC USE:

No overall differences in safety or effectiveness were observed between these subjects & younger subjects.

ADVERSE REACTIONS:

Adverse events with Rabeprazole are mild to moderate in intensity and included malaise, diarrhea, nausea, skin eruptions, headache and dizziness. Abnormal laboratory findings (increased hepatic enzymes, LDH, blood urea nitrogen) observed with Rabeprazole were similar in incidence and severity with comparator agents and reversible with cessation of therapy.

OVERDOSAGE:

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

STORAGE:

- Store at temperatures not exceeding 30° C.
- Protect from light and moisture
- Keep out of reach of children

AVAILABILITY: USP Type 1 Clear Glass Vial with red flip-off seal x 10 ml (Box of 1's)

CAUTION:

Food, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Manufactured by :
GUFIC BIOSCIENCES LIMITED
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For : **MEGA LIFESCIENCES (AUSTRALIA) PTY LTD**
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We care

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