For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Rx Rabeprazole Sodium Injection IP 20 mg

RABEZCAN-20 Lyophilized Powder

Injection

FOR INTRAVENOUS ADMINISTRATION ONLY

Composition :

Each vial contains :

Rabeprazole Sodium (Sterile) (Lyophilized) IP 20 mg

Description

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^+- AT Pase 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.

Indications

It is an alternative in patients for whom oral administration of Rabeprazole is not indicated.

Rabezcan-20 Injection is indicated in the treatment of:

1.Sequential therapy (step-up) from oral **Rabezcan-20**, e.g. A patient previously on oral **Rabezcan-20** who is temporarily unable to take oral medication for any reason.

2.Active duodenal ulcer with bleeding or severe erosions.

3.Active gastric ulcer with bleeding or severe erosions.

4.Short-term treatment of erosive or ulcerative gastroesophageal reflux disease (GERD)

Geriatric use

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

Side Effects

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 below 25°C till reconstitution. Protected from light & moisture.
Improper storage may deteriorate the product.

Presentation

Rabezcan-20 Injection is available in a vial of 5 ml with Sterile water for injection IP

Manufactured by:

AMERICAN REMEDIES ©
Care & Cure with Research

American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)

ICO: American Remedies LLC, DE, USA

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5. Prevention of acid-aspiration
6. Stress-induced mucosal injury in critical care
7. Pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

Dosage 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

Rabezcan-20 Injection is compatible with Sterile water for Injection IP. And 0.9% w/v Sodium chloride Injection IP. No other solvent or Infusion fluid must be used for Administration of **Rabezcan-20** 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 excercised 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 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 10.8 - 12.5

Contraindications

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

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 enzymatially. 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 excercised when Rabeprazole is administered to a nursing mother.

Paediatric use

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