140 x 215mm

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# Rabeprazole Injection IP 20 mg

## RABIJET™-20

Lyophilized Powder
Single Use Vial
For L.V. Use Only

**Composition:**

Each vial contains:

Rabeprazole Sodium IP.....20 mg

(Sterile Lyophilized Powder)

**Dosage Form :**

For intravenous (I.V.) administration only.

**Pharmacology**

**Mechanism of Action**

Rabeprazole sodium 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 within the parietal cell, Rabeprazole has been characterized as a gastric PPI. Rabeprazole blocks the final step of gastric acid secretion.

In gastric parietal cells, Rabeprazole is protonated, accumulates, and is transformed to an active sulphenamide. When studied in vitro, Rabeprazole is chemically activated at pH 1.2, with a half-life of 78 seconds. It inhibits acid transport in porcine gastric vesicles, with a half-life of 90 seconds.

**Antisecretory Activity**

The antisecretory effect begins within 1hour after oral administration of 20 mg Rabeprazole sodium. The median inhibitory effect of rabeprazole sodium on 24-hour gastric acidity is 88% of maximal after the first dose. Rabeprazole sodium 20 mg inhibits basal and peptone meal-stimulated acid secretion versus placebo by 86% and 95%, respectively, and increases the percent of a 24-hour period that the gastric pH>3 from 10% to 65% (see table below). This relatively prolonged pharmacodynamic action, compared with the short pharmacokinetic half-life (1-2 hours), reflects the sustained inactivation of the H+, K+ATPase.

**Indications**

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

AKURAB I.V. is indicated in the treatment of the following:

Sequential-therapy (step-up) from oral Rabeprazole, e.g. a patient previously on oral Rabeprazole who is temporarily unable to take oral medication for any reason.
Active duodenal ulcer with bleeding or severe erosions.
Active gastric ulcer with bleeding or severe erosions.
Short-term treatment of erosive or ulcerative GERD
Prevention of acid aspiration.
Stress-induced mucosal injury in critical care.
Pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

**Dosage and Administration**

The I.V. administration is recommended only in cases where oral administration is not indicated. As soon as an oral therapy is possible the I.V. therapy should be discontinued.

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Recommended dose is I.V. administration of the content of one vial (20 mg Rabeprazole) once daily.

Parenteral routes of administration other than I.V. 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 minutes.

Infusion: For I.V. infusion, the reconstituted solution should be further diluted and administered as a short-term infusion over 15-30 minutes.

**Contraindications**

AKURAB I.V. is contraindicated in patients with a known hypersensitivity to Rabeprazole or to any component of the formulation.

**Warnings and Precautions**

Presence of Gastric Malignancy

Symptomatic response to therapy with Rabeprazole does not preclude the presence of gastric malignancy.

Patients with healed GERD were treated for up to 40 months with Rabeprazole and monitored with serial gastric biopsies. Patients without H.pylori infection (221 of 326 patients) had no clinically important pathologic changes in the gastric mucosa. Patients with H. pylori infection at baseline (105 of 326 patients) had mild or moderate inflammation in the gastric body or mild inflammation in the gastric antrum. Patients with mild grades of infection or inflammation in the gastric body tended to change to moderate, whereas those graded moderate at baseline tended to remain stable. Patients with mild grades of infection or inflammation in the gastric antrum tended to remain stable. At baseline, 8% of patients had atrophy of glands in the gastric body and 15% had atrophy in the gastric antrum. At endpoint, 15% of patients had atrophy of glands in the gastric body and 11% had atrophy in the gastric antrum. Approximately 4% of patients had intestinal metaplasia at some point during follow-up, but no consistent changes were seen.

**Overdosage**

There has been no experience with large overdoses with Rabeprazole. Seven reports of accidental overdosage with Rabeprazole have been received. The maximum reported overdose was 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 q.d.

No specific antidote for Rabeprazole is known. Rabeprazole is extensively protein-bound and is not readily dialysable. In the event of overdosage, treatment should be symptomatic and supportive.

**Storage:** Store at a temperature not exceeding 25°C. Do not allow to freeze

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