SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Product Name **:** Barole I.V Injection (Rabeprazole Sodium 20 mg)

Strength **:** 20 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Rabeprazole Sodium 20 mg

Each vial contains:

Rabeprazole sodium	20 mg
Excipients	q.s

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Off white lyophilized cake and / or powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

Rabeprazole Injection is indicated in the treatment of:

1. Active duodenal ulcer with bleeding or severe erosions.
2. Active gastric ulcer with bleeding or severe erosions.
3. Short-term treatment of erosive or ulcerative gastroesophageal reflux disease (GERD)
4. Prevention of acid-aspiration during surgery.
5. Prevention of stress-induced mucosal injury in critical care.
6. Pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

4.2 Posology and method of 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 slowlyover5-15 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:

Barole Injection is not 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 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. 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 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, impairment, caution should be excercised in these patients. 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 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

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4.3 Contraindications

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

4.4 Special warnings and precautions for use

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.

4.5 Interaction with other medicinal products and other forms of interaction

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.

4.6 Pregnancy and lactation

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.

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

4.7 Effects on ability to drive and use machines - NA

4.8 Undesirable 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.

4.9 Overdose

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties:

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.

5.2 Pharmacokinetic properties

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 plasma½ 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 glucourinide, and mercapturic acid metabolites. These metabolites were not observed to have significant anti-secretory activity. No unchanged Rabeprazole is recovered in the urine or faeces.

5.3 Preclinical safety data - NA

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol, Sodium Hydroxide, Water for injection.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C in a dry place

Protect from light and moisture

Keep out of reach of children

6.5 Nature and contents of container

Barole Injection is available as a sterile freeze dried powder for reconstitution. 20 mg Rabeprazole sodium / vial of 10 ml. 1 vial/ carton.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements;

7. MARKETING AUTHORISATION HOLDER-

Marketed by:

Mega Lifesciences Nigeria Limited

6B Guinness road, Ogba, Ikeja, Lagos.

Manufactured by:

Gufic Biosciences Limited

N.H No. 8, Near Grid, Kabilpore,

Navsari, Gujarat, India