1.3.1

Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

1.1 Name of the medicinal Product

Rabeprazole Tablets 20 mg

1.2 Strength

Each Enteric Coated Tablet Contains:

Rabeprazole Sodium 20 mg

Excipients Q.S.

Colour: Yellow Oxide of Iron & Titanium Dioxide BP

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Rabeprazole Sodium

2.2 Quantitative Declaration

Sr. No.	Ingredients	Specifications	Label Claim (mg/Tablet)	Function
1	Rabeprazole Sodium	IH	20.00	Antibacterial
2	Mannitol	BP	21.50	Diluent
3	Light Magnesium Oxide	USP	22.00	Diluent
4	Crospovidone (Polyplasdone)	USP-NF	11.00	Glidant
5	Hydroxypropyl Cellulose	IH	1.00	Binder
6	Methanol	BP	Q.S.	Disintegrant
7	Microcrystalline Cellulose (PH 112)	IH	24.00	Lubricant
8	Purified Talc	BP	1.500	Glidant
9	Colloidal Anhydrous Silica	BP	1.000	Lubricant
10	Magnesium Stearate	BP	2.000	Lubricant
11	Sheffcoat	IH	4.800	Coating Agent
12	Methanol	BP	36.00	Solvent
13	Dichloromethane	BP	55.20	Solvent
14	Sheffcoat ENT-MA	IH	14.40	Coating Agent

15	Purified Water	BP	57.60	Solvent

3. Pharmaceutical Form

Enteric Coated Tablets.

Yellow coloured, round shaped, biconvex, plain on both side, enteric coated tablets.

4. Clinical Particulars

4.1 Therapeutic Indications

RABEPRAZOLE TABLETS are indicated for the treatment of

Active duodenal ulcer

Active benign gastric ulcer

Symptomatic erosive or ulcerative gastro-oesophageal reflux disease (GORD).

Gastro-Oesophageal Reflux Disease Long-term Management (GORD Maintenance)

Symptomatic treatment of moderate to very severe gastro-oesophageal reflux disease (symptomatic GORD)

Zollinger-Ellison Syndrome

In combination with appropriate antibacterial therapeutic regimens for the eradication of Helicobacter pylori in patients with peptic ulcer disease

4.2 Posology and Method of Administration

Adults/elderly: Active Duodenal Ulcer and Active Benign Gastric Ulcer: The recommended oral dose for both active duodenal ulcer and active benign gastric ulcer is 20mg once daily in the morning. Treatment should continue for as long as clinically indicated.

Erosive or Ulcerative Castro-Oesophageal Reflux Disease (CORD): 20mg to be taken once daily for four to eight weeks.

Castro-Oesophageal Reflux Disease Long-term Management (GORD Maintenance): For long-term management, a maintenance dose of RABEPRAZOLE TABLETS 20 mg or 10 mg once daily can be used depending upon patient response.

Zollinger-Eilison Syndrome: Starting dose is 60 mg once a day. The dose may be titrated upwards to 120 mg/day based on individual patient needs. Single daily doses up to 100 mg/day may be given. 120mg dose may require divided doses, 60 mg twice daily. Treatment should continue for as long as clinically indicated.

Eradication of H. pylori: It is indicated for H.Pylori positive duodenal ulcers, as part of the eradication programme with appropriate antibiotics.

Renal and hepatic impairment: No dosage adjustment is necessary for patients with renal or mild hepatic impairment.

Children: RABEPRAZOLE TABLETS is not recommended for use in children, as there is no experience of its use in this group.

Direction for use: For indications requiring once daily treatment RABEPRAZOLE TABLETS should be taken in the morning, before eating; and although neither the time of day nor food intake was shown to have any effect on Rabeprazole sodium activity, this regimen will facilitate treatment compliance.

Patients should be cautioned that the RABEPRAZOLE TABLETS should not be chewed or crushed, but should be swallowed whole.

4.3 Contraindications

RABEPRAZOLE TABLET is contra-indicated in patients with known hypersensitivity to rabeprazole sodium, or to any excipient used in the formulation.

RABEPRAZOLE TABLET is contraindicated during pregnancy and should not be used during breast feeding.

4.4 Special Warnings and Special Precautions for Use

Atrophic gastritis: Long-term omeprazole therapy has caused atrophic gastritis (by biopsy); this may also occur with rabeprazole.

Fractures: Increased incidence of osteoporosis-related bone fractures of the hip, spine, or wrist may occur with proton pump inhibitor (PPI) therapy.

Hypomagnesaemia: Prolonged PPI use of > 3 months (most cases > I year of therapy) may cause hypomagnesemia in some patients. Hence caution is required while using for prolong period.

Gastric or esophageal malignancy: Symptomatic response to therapy with rabeprazole sodium does not preclude the presence of gastric or esophageal malignancy, therefore the possibility of malignancy should be excluded prior to commencing treatment with RABEPRAZOLE TABLETS.

Dyscrasias: RABEPRAZOLE TABLETS may cause blood dyscrasias (thrombocytopenia and neutropenia) and hence caution is required.

Gastrointestinal infection (e.g., Salmonella, Campyiobacter): Use of proton pump inhibitors may increase risk of these infections.

Sever Hepatic impairment: Use caution in patients with severe hepatic impairment.

4.5 Interaction with other medicinal products and other forms of interaction

Rabeprazole is metabolized by the cytochrome P450 (CYP450) drug metabolizing enzyme system. Rabeprazole docs not have clinically significant interactions with other drugs metabolized by the CYP450 system, such as warfarin, theophylline, diazepam and phenytoin.

Rabeprazole produces sustained inhibition of gastric ac id secretion. An interaction with compounds which are dependent on gastric pH for absorption like ketoconazole may occur due to the magnitude of acid suppression observed with rabeprazole.

Therefore, patients may need to be monitored when such drugs are taken concomitant ly with rabeprazole. Co-administration of rabeprazole and antacids produced no clinically relevant changes in plasma rabeprazole concentrations.

4.6 Fertility, Pregnancy and Lactation

Pregnancy: There are no data on the safety of rabeprazole in human pregnancy. Reproduction studies performed in rats and rabbits have revealed no evidence of impaired fertility or harm to the foetus due to rabeprazole sodium, although low foetoplacental transfer occurs in rats. Rabeprazole 20 mg Gastro-resistant Tablets is contraindicated during pregnancy.

Lactation: It is not known whether rabeprazole sodium is excreted in human breast milk. No studies in lactating women have been performed. Rabeprazole sodium is however excreted in rat mammary secretions. Therefore Rabeprazole 20 mg Gastroresistant Tablets must not be used during breast feeding.

4.7 Effects on ability To Drive and use Machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable Effects

The majority of side-effects are gastrointestinal in origin with anorexia, nausea, abdominal Common adverse events: Infection, Insomnia, Headache, Dizziness, Cough, Pharyngitis, Rhinitis, Diarrhoea, Vomiting, Nausea, Abdominal pain, Constipation, Flatulence, Non-specific pain, Back pa in, Asthenia and Influenza like illness

Uncommon adverse events: Nervousness, Somnolence, Bronchitis, Sinusitis, Dyspepsia, Dry mouth, Eructation, Rash, Erythema, Myalgia, Leg cramps, Arthralgia, Urinary tract infection, Chest pain, Chills, Pyrexia, Increased hepatic enzymes.

4.9 Overdose

Experience to date with deliberate or accidental overdose is limited. The maximum established exposure has not exceeded 60 mg twice daily, or 160mg once daily. Effects are generally minimal, representative of the known adverse event profile and reversible without further medical intervention. No specific antidote is known. Rabeprazole sodium is extensively protein bound and is, there fore, not dialyzable. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilized.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Anti Ulcerative

Rabeprazole is a partially reversible inhibitor of H1<+ ATPase which is activated in the acidic lumen of the gastric parietal cells. The canalicular membrane of the gastric parietal cells contains the proton pump · H+K+ ATPase enzyme. It exchanges H+ ions for K+ ions using energy generated by the breakdown of ATP to ADP. This enzyme represents the final step for acid reduction in the stomach. It dissociates more quickly and completely from H+ /K+ ATPase than Omeprazole.

5.2 Pharmacokinetic Properties

Rabeprazole after oral administration, absorption is rapid with peak plasma levels of rabeprazole occurring approximately 3.5 hours after 20 mg dose. Absolute bioavailability is about 52%, and plasma half life is approximately one hour. 97% of rabeprazole is bound to human plasma proteins. Approximately 90% of rabeprazole was eliminated in the urine, primarily as thioether carboxylic acid; its glucuronide, and mercapturic acid metabolites. The

remainder of the dose was recovered in the feces. No unchanged rabeprazole was recovered in the urine or feces.

5.3 Preclinical Safety Data

Not Applicable

6 Pharmaceutical Particulars

6.1 List of Excipients

Mannitol BP

Light Magnesium Oxide BP

Crospovidone (Polyplasdone) USP-NF

Hydroxypropyl Cellulose IH

Methanol BP

Microcrystalline Cellulose (PH 112) BP

Colloidal Anhydrous Silica (Aerosil) BP

Purified Talc BP

Magnesium Stearate BP

Sheffcoat IH

Dichloromethane BP

Sheffcoat-ENT-MA IH

Purified Water BP

6.2 Incompatibilities

None.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30^0C. Protect from light and moisture.

6.5 Nature and Contents of Container

Yellow coloured, round Shaped, biconvex, plain on both sides, enteric coated tablets. 10 tablets are packed in Alu-Alu blister pack. 3 Blister packed in printed carton along with packaging insert.

6.6 Special precaution for disposal and other handling

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

7. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)

7.1 Name and Address of Marketing Authorization Holder

GENERICS AND SPECIALITIES LTD.

31, AWONIYI ELEMO STREET,

OFF LATEEF SALAMI STREET.

AJAO ESTATE, LAGOS,

NIGERIA.

E-mail: info@zolonhealthcare.com

7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Telephone no.: +91-07949-135000

Fax: +91-02764-281809

Email: info@lincolnpharma.com

Website: www.lincolnpharma.com

7.3 Marketing Authorization Number

To be included after obtaining first registration.

7.4 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

8. Date of Revision of the Text

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9. Dosimetry (If Applicable)

Not Applicable

10. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable