Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

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Gastro-Resistant Omeprazole Capsules BP 20 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard gelatin capsule contains:

Omeprazole BP 20mg (As Enteric Coated Pellets)

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Hard Gelatin Capsules

Brick white/ brick pink hard gelatin capsules of size "2", containing white to off white enteric coated pellets.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Drug is indicated in:

- Treatment of reflux oesophagitis disease.
- Treatment of duodenal and benign gastric ulcers including complicating NSAID therapy.
- Relief of reflux-like symptoms (e.g. heartburn) and/or ulcer-like symptoms (e.g. epigastric pain) associated with acid-related dyspepsia.
- Treatment and prophylaxis of NSAID-associated benign gastric ulcers, duodenal ulcers and gastroduodenal erosions in patients with a previous history of gastroduodenal lesions who require continued NSAID treatment.
- Relief of associated dyspeptic symptoms.
- Prophylaxis of acid aspiration.
- Zollinger-Ellison syndrome.

4.2 Posology and Method of administration

Method of administration: Oral

Omeprazole capsules should be swallowed whole not to be opened, chewed or crushed.

<u>Posology in adults</u>

Treatment of duodenal ulcers

20mg once daily, for 2 weeks. Maximum 40mg once daily for 4 weeks.

Prevention of relapse of duodenal ulcers

10- 20mg once daily. the dose can be increased to 40mg.

Treatment and Prevention of relapse of gastric ulcers

20mg once daily for 4 weeks. Maximum 40mg for 8 weeks.

Treatment of reflux oesophagitis and symptomatic gastro-oesophageal reflux disease & Prevention of NSAID-associated gastric and duodenal ulcers

20mg once daily for 4 weeks.

Treatment of Zollinger-Ellison syndrome

60mg daily. When dose exceed Omeprazole 80mg daily, the dose should be divided and given twice daily.

Children over 1 year of age and ≥10kg

Treatment of reflux oesophagitis(4-8 weeks) , Symptomatic treatment of heartburn and acid regurgitation in gastro-oesophageal reflux disease (2-4 weeks)

The posology recommendations are as follows:

≥ 1 year of age 10-20kg 10mg once daily. The dose can be increased to 20mg once daily if needed.

≥ 2 years of age > 20kg 20mg once daily. The dose can be increased to 40mg once daily if needed.

4.3 Contraindications

- Hypersensitivity to omeprazole, substituted benzimidazoles or to any of the excipients.
- Omeprazole like other proton pump inhibitors (PPIs) must not be used concomitantly with nelfinavir.

4.4 Special warnings and precautions for use

- Treatment with acid-reducing drugs may lead to a slightly increased risk of gastrointestinal infections, such as *Salmonella* and *Campylobacter*.
- Some children with chronic illnesses may require long-term treatment although it is not recommended.

4.5 Interaction with other medicinal products and other forms of interact.

- Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin, drugs that are metabolized by oxidation in the liver.
- Omeprazole may interfere with absorption of drugs eg, ketoconazole, ampicillin esters, and iron salts.
- Co-administration of omeprazole and clarithromycin have resulted in increases in plasma levels of omeprazole, clarithromycin, and 14-hydroxy-clarithromycin.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

Well-conducted epidemiological studies indicate no adverse effects of Omeprazole on pregnancy or on the health of the foetus/new-born child. Omeprazole 20 mg can be used during pregnancy.

Lactation

Omeprazole is excreted into breast milk but is unlikely to influence the child when used in therapeutic doses.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

Constipation, cough, dizziness or back pain may occur, signs of vitamin B-12 deficiency with long-term (over 3 years) treatment e.g., unusual weakness, sore tongue, numbness or tingling of the hands/feet, rash, itching, swelling, severe dizziness, trouble breathing.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Confusion, unusual sweating, blurred vision, unusually fast heartbeat.

There is no specific antidote for overdose with omeprazole; treatment should be symptomatic and supportive.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Omeprazole reduces gastric acid secretion through a unique mechanism of action. It is a specific inhibitor of the gastric proton pump in the parietal cell. It is rapidly acting and produces reversible inhibition of gastric acid secretion with once daily dosing

5.2 Pharmacokinetic properties

Absorption

Absorption takes place in the small intestine and is usually completed within 3 – 6 hours. The systemic bioavailability of omeprazole from a single oral dose is approximately 35%.

Protein binding:

The plasma protein binding of omeprazole is about 95%.

Metabolism

Omeprazole is entirely metabolised, mainly in the liver. The average half-life of the terminal phase of the plasma concentration-time curve is approximately 40 minutes.

Elimination:

About 80% of the metabolites are excreted in the urine and the rest in the faeces.

5.3 Preclinical safety data

Non Stated

6.0 Pharmaceutical particulars

6.1 List of excipients

Dummy pellets, Empty hard gelatin capsules of size "2", brick white/ brick pink.

6.2 Incompatibilities

None reported

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store at temperature not exceeding 30°C in a dry place. Protect from light.

6.5 Nature and contents of container

Strip Pack of 10 x 10 Capsules, such strips are packed in a unit carton along with package insert.

6.6 Special precautions for disposal and other handling

None reported

7. Marketing Authorisation Holder

MEDICAMEN BIOTECH LIMITED

SP-1192 A & B, Phase-IV,
Industrial Area, Bhiwadi-301019,
Distt Alwar, Rajasthan India

8. Number(s) in the national register of finished pharmaceutical products

Certificate No: 06012/07792/REN/2021

9. Date of first authorisation/renewal of the authorisation

May 26, 2021

10. Date of revision of the text

July 2023