1.3.1

Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

1.1 Name of the medicinal Product

Omeprazole Capsules 20 mg

1.2 Strength

Each Hard Gelatin Capsule contains:

Omeprazole BP 20 mg

(As enteric coated granules)

Excipients Q.S.

Approved colours used in empty capsule shell.

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Omeprazole BP

2.2 Quantitative Declaration

Sr. No.	Ingredients	Specifications	Label Claim (mg/Capsule)	Function
1	Omeprazole Pellets (7.15%w/w)	IH	280.00	Proton Pump Inhibitor
2	Pink/white Size “2” hard gelatin Capsules	IH	1.0	Empty Capsule Shell

3. Pharmaceutical Form

Hard Gelatin Capsules.

Pink/white color size “2” capsule containing white to off-white coloured round enteric coated pellets.

4. Clinical Particulars

4.1 Therapeutic Indications

Omeprazole is used to treat the following conditions:

Treatment of Oesophageal reflux disease

Acid indigestion (dyspepsia) which can cause stomach pain and/or discomfort.

Treatment of duodenal and benign gastric ulcers including those complicating NSA!Ds therapy. Ulcers which arc infected with bacteria called Helicobacter pylori .

Treatment and prophylaxis of NSAID-associated benign gastric ulcers, duodenal ulcers and gastro duodenal erosions in patients with a previous history of gastro duodenal lesions who require continued NSAI D treatment.

Prophylaxis of acid aspiration.

Zollinger-Ellison syndrome.

4.2 Posology and Method of Administration

Do not chew or crush the capsule. Swallow as a whole.

Adults: Oesophageal reflux disease including reflux oesophagitis: The usual starting dose is 20 mg omeprazolc taken once a day for 4 weeks. For those patients not fully healed after the initial 4 week course, healing usually occurs during a further 4-8 weeks treatment.

Omeprazole has also been used in a dose of 40mg once a day in patients with reflux oesophagitis refractory to other therapy. Healing usually occurred within 8 weeks. Continuation of therapy can be considered at a dosage of20 mg once daily.

Acid reflux disease: For long-term management, a dose of l 0 mg once daily is recommended, increasing to 20 mg if symptoms return.

Duodenal and benign gastric ulcers: The usual dose is 20 mg Omeprazole once daily. With duodenal ulcers, the majority of patients usually are healed after 4 weeks of treatment. The majority of patients with benign gastric ulcer arc healed after 8 weeks. In severe or recurrent cases the dose may be increased to 40 mg omeprazole daily.

Acid-related dyspepsia: Usual dosage is 10 mg or 20 mg Omeprazole once daily for 2 - 4 weeks depending on the severity and persistence of symptoms.

For the treatment of NSAID-associated gastric ulcers, duodenal ulcers or gastro duodenal erosions: The recommended dosage of Omeprazole is 20 mg once daily. Symptom resolution is rapid and in most patients healing occurs within 4 weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a furthcr4 weeks treatment.

For the prophylaxis of NSAID-associated gastric ulcers, duodenal ulcers, gastro duodenal erosions and dyspeptic symptoms in patients with a previous history of gastro

duodenal lesions who require continued NSAID treatment: The recommended dosage is 20 mg Omeprazole taken once a day.

Helicobacter pylori (Hp) eradication regimens in peptic ulcer disease: Omeprazole is recommended at a dose of 40 mg once daily or 20 mg twice daily concomitant with antimicrobial agents.

Prophylaxis of acid aspiration: For patients considered to be at risk of aspiration of the gastric contents during general anaesthesia, the recommended dosage is Omeprazole 40 mg on the evening before surgery followed by a further 40 mg 2- 6 hours prior to surgery.

Zollinger-Ellison Syndrome: The initial starting dose is Omeprazole 60 mg once a day. The dosage should be adjusted individually and treatment continued as long as clinically indicated. More than 90% of patients with severe disease and inadequate response to other therapies have been effectively controlled on doses of20- 120 mg daily. With doses above 80 mg daily, the dose should be divided and given twice daily.

Elderly: No dosage adjustment is required.

Children (1-16 years)

10 kg to < 20 kg: 10 mg once daily. The dosage can be increased to 20 mg once daily if needed.

≥ 20 kg: 20 mg once daily. The dosage can be increased to 40 mg once daily if needed.

Reflux oesophagitis: The treatment time is 4- 8 weeks.

Symptomatic treatment of heart burn and acid regurgitation in gastroesophageal reflux Disease: The treatment time is 2-4 weeks. If symptom control has not been achieved after 2-4 weeks the patient should be investigated further.

For patients (including children aged l year and above who can drink or swallow semi-solid food) who arc unable to swallow

Omeprazole Capsules: The capsules may be opened and the contents swallowed directly with half a glass of water or suspended in 10 ml of non-carbonated water, any fruit juice with a pH less than 5 e.g. apple, orange, pineapple, or in applesauce or yoghurt and swallowed after gentle mixing. The dispersion should be taken immediately or within 30 minutes. Stir just before drinking and rinse it down with half a glass of water. Alternatively the actual capsules may be sucked and then swallowed with half a glass of water. There is no evidence to support the use of sodium bicarbonate buffer as a delivery form.

Renal impairment: No dosage adjustment is required.

Impaired hepatic function: As bioavailability and half-life can increase in patients with impaired hepatic function, the dose requires adjustment with a maximum daily dose of 20mg.

4.3 Contraindications

Omeprazole Capsules is contraindicated in the Patients with a history of hypersensitivity to Omeprazole or to any of the excipients of this product.

4.4 Special Warnings and Special Precautions for Use

Relief of symptoms docs not preclude the presence of a gastric malignancy.

Use of Omeprazole Capsules may increase risk of gastrointestinal infection (cg, Salmonella, Campylobacter).

Bioavailability of the Omeprazole may be increased in patients with hepatic dysfunction; consider dosage reductions, especially for maintenance healing of erosive esophagitis.

Some children with chronic illnesses may require long-term treatment al though it is not recommended.

Pregnancy: Omeprazole Capsules can be used during pregnancy only if the potential benefit to the mother outweighs the possible risk to the fetus.

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

4.5 Interaction with other medicinal products and other forms of interaction

Due to the decreased intragastric acidity the absorption of ketoconazole or itraconazole may be reduced during Omeprazole treatment as it is during treatment with other acid secretion inhibitors.

Omeprazole may increase the serum concentration of Vitamin K Antagonists.

Plasma concentrations of Omeprazole and clarithromycin arc increased during concomitant administration.

Simultaneous treatment with Omeprazole and digoxin in healthy subjects lead to a 10% increase in the bioavailability of digoxin as a consequence of the increased intragastric pH.

Omeprazole may decrease the serum concentration of Atazanavir.

Concomitant administration of Omeprazole and tacrolimus may increase the serum levels of tacrolimus.

Concomitant administration of Omeprazole and a CYP2Cl9 and CYP3A4 inhibitor, voriconazole, resulted in more than doubling of the Omeprazole exposure.

Omeprazole may increase the serum concentration of Benzodiazepines (metabolized by oxidation).

4.6 Fertility, Pregnancy and Lactation

Pregnancy: Omeprazole Capsules can be used during pregnancy only if the potential benefit to the mother outweighs the possible risk to the fetus.

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

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

4.8 Undesirable Effects

Central nervous system: Headache, dizziness.

Dermatologic: Rash

Gastrointestinal: Abdominal pain, diarrhea, nausea, vomiting, flatulence, acid regurgitation, constipation.

Neuromuscular & skeletal: Back pain, weakness.

Respiratory: Upper respiratory infection, cough.

4.9 Overdose

Overdosage of Omeprazole is reported to be associated with nausea, vomiting, dizziness, abdominal pain, diarrhea and headache.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Proton Pump Inhibitor

Omeprazole inhibits the secretion of gastric acid by irreversibly blocking the enzyme system of H+/K + ATPase of the gastric parietal cell. It is activated at an acidic pH to a sulphenamide derivative that binds irreversibly to H+/K+ ATPase, an enzyme system found at the secretory

surface of parietal cells. It thereby inhibits the final transport of hydrogen ions (via exchange with K ions) into the gastric lumen.

5.2 Pharmacokinetic Properties

Absorption: Omeprazole is acid labile and is administered orally as enteric-coated granules in capsules. Absorption takes place in the small intestine. Peak plasma concentrations of omeprazole occur within Ito 3 hours after administration. The systemic bioavailability of Omeprazole from a single oral dose is approximately 35%. After repeated once-daily administration, the bioavailability increases to about 60%. Concomitant intake of food has no influence on the bioavailability.

Distribution: The distribution volume of Omeprazole in the body is relatively small (0.3 l/kg of body weight) and corresponds to that of the extracellular liquid. The plasma protein binding of omeprazole is about 95%.

Metabolism and Elimination: Omeprazole is entirely metabolized, mainly in the liver. Identified metabolites in plasma arc the sulfone, the sulfide and hydroxy-omeprazole, these metabolites have no significant effect on acid secretion. The plasma half-life is about 40 minutes and the total plasma clearance is 0.3 to 0.6 V min. About 20% of administered dose is excreted in faeces and the remaining 80% is excreted in urine as metabolites. The two major urinary metabolites arc hydroxy-omeprazole and the corresponding carboxylic acid.

5.3 Preclinical Safety Data

Not Applicable

6 Pharmaceutical Particulars

6.1 List of Excipients

Omeprazole Pellets (7.15% w/w) IH

Capsule Shell Pink/white Size ”2” IH

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

Pink/white color size "2" capsule containing white to off-white coloured round enteric coated pellets. 7 tablets are packed in Alu-Alu blister pack. 2 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: +91-07941-078062

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