1.6.1.1 Name of the medicinal Product

Omeprazole Delayed Release Capsules USP 20 mg

1.6.1.1.1 strength

20 mg

1.6.1.1.2 Pharmaceutical Form

Oral Tablet

1.6.1.2 Qualitative and Quantitative Composition

1.6.1.2.1 Qualitative declaration

Omeprazole USP

1.6.1.2.2 Quantitative declaration

Sr. No.	Ingredients Chemical Name	Specification	Standard Quantity (per unit gm)	Reason for Inclusion
01	Omeprazole Pellets (7.15 w/w) (A)	IH	280.00	Proton pump Inhibitor
02	Pink/white Size "2" hard gelatin Capsule	IH	1.00	Empty Capsule Shell

Note:

(A) = Quantity to be calculated on the basis of its potency.

% assay is more than 100%, in that case target weight consider as 280 mg.

280 mg of omeprazole pellets (7.15%w/w) equivalent to omeprazole 20 mg.

1.6.1.3 Pharmaceutical Form

Hard gelatin Capsule

Pink/white color size "2" capsule containing white to off-white coloured round enteric coated Pellets.

1.6.1.4 Clinical Particulars

1.6.1.4.1 Therapeutic Indications

Omeprazole Capsule is used in the treatment of duodenal ulcer, gastric ulcer, reflux oesophagitis (gastro-oesophageal reflux) and Zollinger-Ellison syndrome.

It is also used in prevention of stress ulcers, acid aspiration syndrome during anaesthesia and treatment of upper gastrointestinal bleeding.

1.6.1.4.2 Posology and Method of Administration

Duodenal Ulcer, Gastric Ulcer and Reflux Oesophagitis : The recommended dosage is 20 mg Omeprazole once daily.

In patients with duodenal ulcer symptoms, relief is rapid and healing occurs within 2 weeks in most cases. For those patients who may not have fully healed after the initial course, healing usually occurs during a further 2-week treatment period.

In patients with gastric ulcer or reflux oesophagi tis symptom, relief is rapid and healing occurs within 4 weeks in most cases. For those patients who may not have fully healed after the initial course, healing usually occurs during a further 4-week treatment period.

In patient's refractory to other treatment regimens, 40 mg Omeprazole once daily has been used and healing achieved, usually within 4 weeks in patients with duodenal ulcer and within 8 weeks in patients with gastric ulcer or reflux oesophagitis.

Zollinger-EIIison Syndrome: The recommended initial dosage is 60 mg Omeprazole once daily. The dosage should be adjusted individually and treatment continued as long as it is clinically indicated. All patients with severe disease and inadequate response to other therapies have been effectively controlled and > 90% of the patients maintained on doses of 20-120 mg daily. With doses >80 mg daily, the dose should be divided and given twice daily.

Children: There is no experience with Omeprazole in children.

Elderly: No dose adjustment is necessary in the elderly.

1.6.1.4.3 Contraindications

Patients with a history of hypersensitivity to omeprazole.

Use in Children: Safety and effectiveness of omeprazole in children have not been established. Omeprazole is not recommended for use in children since no adequate data are available.

1.6.1.4.4 Special Warnings and Special Precautions for Use

Maintenance therapy : Omeprazole should not be used as maintenance therapy for treatment of patients with duodenal ulcer disease. Duration of therapy (GERD): The efficacy of Omeprazole used for > 8 weeks has not been established. In the rare patient not responding to 8 weeks of treatment, an additional4 weeks of treatment may help. If there is recurrence of erosive or symptomatic GERD poorly responsive to customary medical treatment, an additional 4 to 8 week course of Omeprazole may be considered.

Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with Omeprazole.

Elderly : Bioavailability may be increased.

Pregnancy: There are no adequate or well controlled studies in pregnant women. Use during pregnancy only if the potential benefit justifies the risk to the foetus.

Lactation: It is not known whether Omeprazole is excreted in breast milk.

Children: Safety and efficacy in children have not been established.

1.6.1.4.5 Interaction with other medicinal products and other forms of interaction

Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin, drugs that are metabolised by oxidation in the liver. Monitoring of patients also receiving warfarin or phenytoin is recommended and a reduction of dose of warfarin and phenytoin may be necessary. However, concomitant treatment with Omeprazole 20 mg daily did not change the blood concentration of phenytoin in patients on continuous treatment with phenytoin. No interaction with propranolol, theophylline, metoprolol, lidocaine or quinidine has been found, but interactions with other drugs also metabolised via the cytochrome P-450 enzyme system cannot be excluded. No interactions with concomitantly administered antacids have been found.

Incompatibilities: None known yet.

1.6.1.4.6 Fertility, Pregnancy and Lactation

No data available.

1.6.1.4.7 Effects on ability To Drive and use Machines

Not Applicable

1.6.1.4.8 Undesirable Effects

Omeprazole Capsule is well tolerated. The following events have been reported, but in the great majority of cases, a consistent relationship between these events and treatment with omeprazole has not been established. Headache, diarrhoea, constipation, abdominal pain, nausea/vomiting and flatulence have been reported at a frequency > 1% by patients treated with omeprazole in clinical trials.

Furthermore, the following events have been reported from marketed use of Omeprazole Capsule:

Rarely : Rash, uticaria and/or pruritus, dizziness, paraesthesia, somnolence, insomnia, vertigo and malaise.

In Isolated Cases: Arthralgia, muscular weakness, myalgia, reversible mental confusion, agitation, depression and hallucination (predominantly in severely ill patients), stomatitis and gastrointestinal candidiasis, increased liver enzymes with or without increased bilirubin values, gynecomastia, leukopenia, thrombocytopenia, peripheral oedema, blurred vision and taste perversion.

Irreversible visual impairment has been reported in isolated cases of critically ill patients who have received omeprazole IV injection, especially at high doses, but no causal relationship has been established.

1.6.1.4.9 Overdose

There is no information available on the effects of overdosage in man and specific recommendations for treatment cannot be given. Single oral doses of up to 160 mg have been well tolerated.

1.6.1.5 Pharmacological Properties

Omeprazole reduces gastric acid secret ion through a highly selective mechanism of action. It produces specific dose dependent inhibition of the enzyme H' -K' -ATPase (the 'proton pump') in the parietal cell. As this action inhibits the final stage of gastric acid formation , there is an effective inhibition of both basal and stimulated acid secretion irrespective of the stimulus to acid formation. Omeprazole has no effect on acetylcholine or histamine receptors and no clinically significant pharmacodynamic effects have been observed other than those explained by the effect of omeprazole on acid secretion. The onset of action is rapid and reversible control of gastric secretion is achieved with once-daily dosing.

Pharmacokinetic: The time to maximum plasma concentration is over 2 hours for enteric-coated granules. Erratic absorption follows administration of the enteric-coated granules as this is dependent on gastric emptying but is of doubtful importance as the plasma concentration/activity relationship is not direct. Although delayed gastric emptying affects peak concentrations, the total amount absorbed and thus available to the parietal cell is unchanged. Maximal plasma concentrations are disproportionate to dosage increments and also relate to the duration of administration. Significant increases in Cmax and AUC follow repeated oral administration over 5 to 7 days. Omeprazole may increase its own bioavailability by inhibiting gastric secretion, thus decreasing pre-absorption activation. It may also saturate its own metabolic pathway.

1.6.1.5.1 Preclinical Safety Data

Not Applicable.

1.6.1.6 Pharmaceutical Particulars

1.6.1.6.1 List of Excipients

Not applicable.

1.6.1.6.2 Incompatibilities

Not applicable.

1.6.1.6.3 Shelf Life

36 months

1.6.1.6.4 Special Precautions for Storage

Store below 30°C. Protect from light & moisture.

1.6.1.6.5 Nature and Contents of Container

Pink/white color size “2” capsule containing white to off-white coloured round enteric coated pellets. 10 Capsules are packed in Alu-strip pack. 10 Alu-strip packed in printed carton along with packaging insert.

1.6.1.6.6 Special precaution for disposal and other handling

The prepared solution should be made up immediately before use.

1.6.1.7 Marketing Authorization Holder And Manufacturing Site Addresses

1.6.1.7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

1.6.1.7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

1.6.1.8 Marketing Authorization Number

To be included after obtaining first registration.

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

It will be applicable after registration of this product.

1.6.1.10 Date of Revision of the Text

1.6.1.11 Dosimetry (If Applicable)

Not Applicable

1.6.1.12 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable