1.3.1

Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

1.1 Name of the medicinal Product

Combipack of Omeprazole For Injection 40 mg & Sterilised Water For Injections BP 10 ml

1.2 Strength

Each Combipack contains:

(A) One vial of Omeprazole For Injections 40 mg

Each vial contains:

Omeprazole Sodium BP (Lyophilised)

Eq. to Omeprazole 40 mg

(B) One Ampoule of 10 ml Sterilised Water For Injections BP

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Omeprazole Sodium BP

2.2 Quantitative Declaration

Sr. No.	Ingredients	Specification	Standard Quantity (mg/vial)	Reason for Inclusion
01	Omeprazole Sodium (Lyophilized) Eq. to Omeprazole	In-house	125.000 Eq. to 40.000	Proton Pump Inhibitor

3. Pharmaceutical Form

Dry Powder for injection

A white lyophilized hygroscopic powder filled in glass vial.

4. Clinical Particulars

4.1 Therapeutic Indications

Omeprazole Injection 40 mg for intravenous use is indicated as an alternative to oral therapy for the following indications:

Treatment of duodenal ulcers;

Prevention of relapse of duodenal ulcers;

Treatment of gastric ulcers;

Prevention of relapse of gastric ulcers;

In combination with appropriate antibiotics, Helicobacterpylori (H.pylori) eradication in peptic ulcer disease;

Treatment of NSA ID-associated gastric and duodenal ulcers;

Prevention of NSAID-associated gastric and duodenal ulcers in patients at risk;

Treatment of reflux oesophagi tis;

Long-term management of patients with healed reflux oesophagi tis;

Treatment of symptomatic gastro-oesophageal reflux disease;

Treatment of Zollinger-Ellison syndrome.

4.2 Posology and Method of Administration

Adults: In patients with duodenal ulcer, gastric ulcer or reflux oesophagitis where oral medication is inappropriate, omeprazole Injection 40 mg once daily is recommended.

In patients with Zollinger-Ellison Syndrome the recommended initial dose of omeprazole injection, given intravenously is 60 mg/daily. Higher daily doses may be required and the dose should be adjusted individually. When doses exceed 60 mg daily, the dose should be divided and given twice daily.

Elderly: Dose adjustment is not needed in the elderly.

Children: There is limited experience with omeprazole IV in children.

Administration: Omeprazole Injection 40 mg should be given as a slow intravenous injection. The solution for IV injection is obtained by adding to the vial 10 mL of the solvent (Water for Injection) provided. (No other solvent should be used). After reconstitution the injection should be given slowly over a period of at least 2.5 minutes at a maximum rate of 4 ml per minute. The solution should be used within 4 hours of reconstitution.

4.3 Contraindications

Hypersensitivity to omeprazole, substituted benzimidazoles or to any of the excipients.

4.4 Special Warnings and Special Precautions for Use

Decreased gastric acidity due to any means, including proton-pump inhibitors, increases gastric counts of bacteria normally present in the gastrointestinal tract. Treatment with acid reducing drugs may lead to a slightly increased risk of

gastrointestinal infections, such as Salmonela and Campylobacter.

In the presence of symptoms such as significant unintentional weight loss, recurrent vomiting, dysphasia, haematemesis, or melaena, and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment with Omeprazole may alleviate symptoms and delay diagnosis.

Impaired Renal Function: Dose adjustment is not needed in patients with impaired renal function.

Impaired Hepatic Function: Bioavailability and plasma half-life of Omeprazole are increased in patients with impaired hepatic function, therefore a daily dose of I 0 -20 mg is generally sufficient.

Pregnancy: Omeprazole Injection 40 mg 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

Co-administration with omeprazole may decrease the serum concentration of Nelfinavir, lndinavir, Atazanavir, Ketoconazole, Cefditoren, Itraconazole, Clozapine, Erlotinib, Posaconazole, Dabigatran Etexilate. Omeprazole may increase the serum concentration of Phenytoin, Benzodiazcpines (metabolized by oxidation), Vitamin K Antagonists(e.g., warfarin), Raltegravir, Cyclosporine, Saquinavir, Tacrolimus, Voriconazole.

Omeprazole may enhance the adverse effect of Cilostazole.

Proton Pump inhibitors (Omeprazole) may diminish the therapeutic effect of Clopidogrel.

Fluconazole may increase the serum concentration of omeprazole.

Omeprazole may decrease the excretion of Methotrexate.

It may be interactions with other medicines, which are also metabolized via the cytochrome P450 enzyme system.

4.6 Fertility, Pregnancy and Lactation

Pregnancy: Omeprazole Injection 40 mg 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

Not Applicable.

4.8 Undesirable Effects

Central nervous system: Headache, dizziness, paraesthesia, light headedness, feeling faint, somnolence, insomnia and vertigo.

Dermatologic: Dermatitis, pruritus, rash, urticaria.

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

Neuromuscular& skeletal: Back pain, weakness.

Respiratory: Upper respiratory infection, cough.

General disorders and administration site conditions: Malaise, peripheral oedema.

4.9 Overdose

There is limited information available on the effects of overdoses of omeprazole in humans. In the literature, doses of up to 560 mg have been described, and occasional reports have been received when single oral doses have reached up to 2,400 mg omeprazole (120 times the usual recommended clinical dose). Nausea, vomiting, dizziness, abdominal pain, diarrhea and headache have been reported.

Treatment: The symptoms of omeprazole overdosage have been transient and no serious outcome has been reported. The rate of elimination was unchanged (first order kinetics) with increased doses. Treatment, if needed, is symptomatic.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Proton Pump Inhibitors

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 l-1/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

Distribution: The apparent volume of distribution in healthy subjects is approximately 0.3 L/kg body weight Omeprazole is 97% plasma protein bound.

Metabolism: Omeprazole is completely metabolized by the cytochrome P450 system, mainly in the liver. The major part of its metabolism is dependent on the polymorphically expressed CYP2C 19 (S-mephenytoin hydroxylase), responsible for the formation of hydroxyomeprazole, the major metabolite in plasma. No metabolite has been found to have any effect on gastric acid secretion.

Excretion: Total plasma clearance is about 0.3 to 0.6 L/min after a single dose. The plasma elimination ha lf-life of omeprazole is usually shorter than one hour both after single and repeated once-daily dosing. Almost 80% of a dose of omeprazole is excreted as metabolites in the urine, the remainder in the faeces, primarily originating from bile secret ion.

5.3 Preclinical Safety Data

Not Applicable

6 Pharmaceutical Particulars

6.1 List of Excipients

Not Applicable

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

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

6.5 Nature and Contents of Container

A white or almost white lyophilized hygroscopic powder filled in 10 ml amber USP type-I glass vial with 20 mm grey butyl rubber stopper and 20 mm blue flip off seal. Such 1 vial is packed with 10 ml sterilised water for injection in printed carton with packing 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 Parenteral Limited

11, Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Telephone no.: +91-02764-665000

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