Losectil®

Omeprazole Powder for Oral Suspension and IV Injection

DESCRIPTION

Losectil® powder for suspension is a preparation of Omeprazole. **Losectil®** 40 IV injection is a combination pack consisting of a vial containing lyophilized powder of Omeprazole Sodium and a separate ampoule of reconstituting solution. Omeprazole is a specific inhibitor of the gastric proton pump (H^+/K^+-ATPase) in the parietal cell, where it produces dose - dependent inhibition of acid secretion by binding to the enzyme and effectively reduces gastric acid secretion. This effect leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus. **Losectil®** powder for oral suspension is formulated as an immediate release one for oral administration. After oral administration, the onset of the antisecretory effect occurs within 1 minute, with the maximum effect occurring within 30 minutes and inhibition of secretion lasts up to 24 hours. When the drug is discontinued, secretory activity returns gradually, over 3 to 5 days.

INDICATIONS

1. Treatment of oesophageal reflux disease.
2. Treatment of duodenal and benign gastric ulcers including those complicating NSAID therapy.
3. Relief of reflux-like symptoms (e.g. heartburn) and / or ulcer like symptoms (e.g. epigastric pain) associated with acid-related dyspepsia.
4. Treatment and prophylaxis of NSAID-associated benign gastric ulcers, duodenal ulcers, and gastroduodenal erosion in-patients with a previous history of gastroduodenal lesions that require continued NSAID treatment.
5. Relief of associated dyspeptic symptoms.
6. *Helicobacter pylori* eradication: Omeprazole should be used in combination with antibiotics for eradication of *Helicobacter pylori* in peptic ulcer disease.
7. Prophylaxis of acid aspiration.
8. Zollinger-Ellison syndrome.

DOSAGE AND ADMINISTRATION

Benign gastric ulcers	20 mg once daily for 8 weeks; in severe or recurrent cases increase to 40 mg daily.
Duodenal ulcers	20 mg once daily for 4 weeks in duodenal ulcer; in severe or recurrent cases increase to 40 mg daily
Maintenance for recurrent duodenal ulcer	20 mg once daily.
Prevention of relapse in duodenal ulcer	10 mg daily increasing to 20 mg once daily if symptoms return.
NSAID-associated peptic ulcer and gastroduodenal erosions	20 mg once daily for 4 weeks, followed by a further 4 weeks if not fully healed.
Prophylaxis in patients with a history of NSAID-associated gastroduodenal lesions who require continued NSAID treatment	20 mg once daily
Zollinger - Ellison syndrome	Initially 60 mg once daily; usual range 20-120 mg daily (above 80 mg in 2 divided doses) orally or intravenously.
Gastric acid reduction during general anaesthesia (prophylaxis of acid aspiration)	40 mg on the preceding evening then 40 mg 2-6 hours before surgery.
Gastro - oesophageal reflux disease	20 mg once daily for 4 weeks, followed by a further 4-8 weeks if not fully healed.
Gastro- oesophageal reflux disease refractory to other treatment	40 mg once daily has been given for 8 weeks may be continued at 20 mg once daily.
Acid reflux disease (long-term management)	10 mg daily increasing to 20 mg once daily if symptoms return.
Acid-related dyspepsia	10-20 mg once daily for 2-4 weeks according to response.
Eradication of *Helicobacter pylori*	20 mg twice daily plus amoxicillin 500 mg four times daily plus metronidazole 400 mg thrice daily for 2 weeks.
Duodenal ulcer, gastric ulcer or reflux oesophagitis where oral medication is inappropriate	**Losectil®** 40 IV injection once daily is recommended.

Paediatric Patients

For the treatment of GERD and maintenance of healing of erosive esophagitis, the recommended daily dose for paediatric patients 1 to 16 years of age is as follows:

Patient Weight	Omeprazole Daily Dose
5 to < 10 kg	5 mg
10 to < 20 kg	10 mg
≥ 20 kg	20 mg

On a per kg basis, the doses of omeprazole required to heal erosive esophagitis in paediatric patients are greater than those for adults.

Impaired renal function: Dose adjustment is not required in patients with impaired renal function.
Impaired hepatic function: As bioavailability and half life may increase in patients with impaired hepatic function, the dose requires adjustment with a maximum daily dose of 20 mg.

METHOD OF ADMINISTRATION

- ❑ **Powder for oral suspension:** Empty the packet contents into a small cup containing 1-2 tablespoon of water. DO NOT USE OTHER LIQUIDS OR FOODS. Stir well and drink immediately.
- ❑ **IV injection:**

For Injection:

Losectil® 40 IV injection 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 provided and no other solvent should be used. Discoloration may occur if incorrect reconstitution technique is 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.

For Infusion:

For IV infusion reconstitute one sterile single dose vial of **Losectil®** 40 IV injection with the provided 10 mL solvent in ampoule to make 10 mL solution containing 4 mg/mL of Omeprazole approximately. Subsequently add this 10 mL reconstituted solution to 90 mL 0.9% Sodium Chloride solution or 90 mL of 5% Dextrose solution to make 100 mL solution of 0.4 mg/mL of Omeprazole approximately. The resultant infusion should be given intravenously over a period of 20-30 minutes. Chemical and physical in-use stability has been demonstrated for 12 hours after reconstitution with saline or for 6 hours after reconstitution with 5% Dextrose. From a microbiological view, the product should be used immediately. Any unused portion should be discarded.

CONTRAINDICATIONS

Omeprazole is contraindicated in patients with known hypersensitivity to active component of the formulation.

USE IN PREGNANCY AND LACTATION

- ❑ **Pregnancy:** Results from three prospective epidemiological studies indicate no adverse effects of Omeprazole on pregnancy or on the health of the foetus / newborn child. Omeprazole can be used during pregnancy.
- ❑ **Nursing mothers:** Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.

SIDE-EFFECTS

Omeprazole is generally well tolerated. Nausea, headache, diarrhoea, constipation and flatulence have been reported but are rare. Skin rashes have occurred in a few patients. These events have usually been mild and transient and there has been no consistent relationship with treatment.

DRUG INTERACTIONS

Omeprazole can delay the elimination of diazepam, phenytoin and warfarin. Monitoring of patients receiving warfarin or phenytoin is recommended and a reduction of warfarin or phenytoin dose may be necessary, when Omeprazole is added to treatment.

PRECAUTIONS

Before treatment the presence of gastric malignancy should be excluded.

PHARMACEUTICAL PRECAUTION

Powder for oral suspension : Store at or below 25° C temperature. Keep away from light & wet place. Keep out of reach of children.

IV injection : Do not store above 25 °C temperature. Keep away from light & wet place. Keep out of reach of children.

PACKAGING

Powder for Oral Suspension :

Losectil® 20 : Each box contains 50 sachets. Each sachet contains Omeprazole USP 20 mg as immediate release formulation.

Losectil® 40 : Each box contains 30 sachets. Each sachet contains Omeprazole USP 40 mg as immediate release formulation.

IV injection:

Losectil® 40 IV injection : Box containing one vial of Omeprazole Sodium BP (as Sterile Lyophilized powder) equivalent to Omeprazole 40 mg and one ampoule of 10 mL Water for Injection USP.

SK+F
Manufactured by
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