Prolok

Omeprazole

Description

Omeprazole is the first drug to be marketed in a group of agents which reduce gastric acid secretion by inhibition of the parietal cell H+-K+ ATPase (the "proton pump"). These drugs are the most potent inhibitors of gastric acid secretionavailable.

Composition

Prolok 20 Capsule: Each capsule contains 20 mg Omeprazole BP as enteric coated pellets. **Prolok 40 Capsule**: Each capsule contains 40 mg Omeprazole BP as enteric coated pellets. **Prolok IV Injection**: Each vial contains 40 mg sterile Lyophilized Omeprazole Sodium BP equivalent to 40 mg Omeprazole.

Indications

Prolok Capsule: Prolok capsule is used for the relief of duodenal ulcer, gastric ulcer, gastroesophageal reflux disease (GERD), GERD with erosive esophagitis, Zollinger-Ellison syndrome, resistant ulcers, eradication of *Helicobacter pylori* in combination with antibiotics, lesions associated with NSAIDs & prevention of acid aspiration syndrome.

Prolok IV injection: Prolok IV is indicated for the treatment of gastric ulcer, duodenal ulcer, reflux esophagitis and also for the treatment of Zollinger-Ellison syndrome.

Disease	**Dose**	**Frequency**
Duodenal ulcer	20 mg	Once daily for 4 to 8 weeks
Gastric ulcer	40 mg	Once daily for 4 to 8 weeks
Gastro-esophageal reflux disease (GERD)	20 mg	Once daily for 4 weeks
GERD with erosive esophagitis	20 mg	Once daily for 4 to 8 weeks
Maintenanceofhealingoferosiveesophagit	20 mg	Once daily *
Zollinger - Ellison syndrome	60 mg	*
Resistant ulcers	*	Once daily for 4 to 8 weeks
Eradication of Helicobacter pyloriin combination with antibiotics	20 mg or 40 mg	*
Lesions associated with NSAIDs	20mg to 40 mg	Once daily *
Prevention of acid aspiration syndrome	*	*

* Depends on the severity of the disease.

Children (over 2 years): Severe ulcerating reflux esophagitis : 0.7-1.4 mg/kg daily for 4-12 weeks; maximum 40 mg daily (to be initiated by hospital pediatricians). **Elderly:** Dosage adjustment is not required in elderly patients. **Prolok IV injection:** In patients with duodenal ulcer, gastric ulcer or reflux esophagitis 40 mg once daily is recommended. In patients with Zollinger-Ellison syndrome, the recommended initial dose 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. Impaired renal function: Dose adjustment is not needed in patients with impaired renal function. Impaired hepatic function: As plasma half-life of Omeprazole is increased in patients with impaired hepatic function, a daily dose of 10 - 20 mg may be sufficient. **Elderly:** Dose adjustment is not needed in the elderly. **Children:** The safety and effectiveness of Omeprazole injection in children have not yet been established.

Method of Administration

Injection: Prolok 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. 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 hour of reconstitution when stored in original vial in a cool place. The reconstituted solution should not be used if it contains visible particulate matter.

Infusion: For IV infusion reconstitute one sterile single dose vial of Prolok IV injection with 10 ml of sterile 0.9% Sodium Chloride solution to make 10 ml solution containing 4 mg/ml of Omeprazole approximately. Subsequently add 10 ml of reconstituted solution containing 4 mg/ml of Omeprazole approximately, 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 hour after reconstitution with saline or for 6 hour after reconstitution with 5% Dextrose. From a microbiological point of view, the product should be used immediately. Any unused portion should be discarded.

Side Effects

Omeprazole is well tolerated and adverse reactions have generally been mild and reversible. Gastrointestinal side effects include diarrhoea, constipation, abdominal pain, nausea/vomiting and flatulence. Central and peripheral nervous system disorders reported include headache, dizziness, paraesthesia, somnolence, insomnia and vertigo. Others include hypersensitivity reactions, e.g angioedema, fever, bronchospasm, interstitial nephritis and anaphylactic shock. Increased sweating, peripheral edema, blurred vision, taste disturbance and hyponatremia.

Contraindications

Patients known to have hypersensitivity to any component of the preparation.

Drug Interactions

The absorption of some medicines might be altered due to the decreased intragastric acidity. As Omeprazole is metabolised in the liver it can prolong the elimination of Diazepam, Warfarin and Phenytoin. Plasma concentrations of Omeprazole and Clarithromycin are increased during concomitant administration but there is no interaction with Metronidazole or Amoxicillin. These antimicrobials are used together with Omeprazole for eradication of *Helicobacter pylori*.

Precautions

Omeprazole should be given in reduced dosage to patients with impaired hepatic function. Use in pregnancy: Results from three prospective epidemiological studies indicate no adverse effects of Omeprazole on pregnancy or on the health of the fetus/newborn child. Omeprazole can be used during pregnancy. Use in lactation: Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used. Like other drugs it should only be used during nursing if considered essential.

Overdosage

Doses up to 400 mg have not resulted in severe symptoms. Symptomatic and supportive therapy should be given as appropriate. Omeprazole IV doses of up to 270 mg on a single day and up to 650 mg over a three-day period have been given in clinical trials without any dose-related adverse reactions.

Pharmaceutical Precautions

Store in a cool and dry place, protected from light. Keep out of the reach of children.

Presentation

Prolok 20 Capsule: Each box contains 10×10 capsules in Alu-Alu blister pack.

Prolok 40 Capsule: Each box contains 3×10 capsules in Alu-Alu blister pack.

Prolok IV Injection: Each combipack contains 1 vial of 40 mg Omeprazole and 1 ampoule of 10 ml of 0.9% Sodium Chloride BP and a sterile disposable syringe (10 ml).

Manufactured by:

IBN SINA

The **IBN SINA** Pharmaceutical Industry Ltd.

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