PROLOK

OMEPRAZOLE BP

Compositions:
Prolok 20 Capsule: Each capsule contains 20 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.

Pharmacology:
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 secretion available.

Dosage And Administration:
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 Maintenance of healing of erosive esophagitis: 20 mg Once daily Zollinger - Ellison syndrome: 60 mg Resistant ulcers * Once daily for 4 to 8 weeks Eradication of Helicobacter pylori in 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.

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

Warning And Precaution:
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.

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.

Use in Pregnancy and Lactation:
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.

Drug Interaction:
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.

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.

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

Packing:
Prolok 20 Capsule: Box containing 10×10 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:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.