PANTOLOK

PANTOPRAZOLE BP

Compositions:
Pantolok 20 tablet: Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate BP equivalent to Pantoprazole 20 mg. Pantolok 40 tablet: Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate BP equivalent to Pantoprazole 40 mg. Pantolok 40 IV injection: Each vial contains Pantoprazole 40 mg (as lyphollized powder of pantoprazole sodium sesquihydrate BP) and each ampoule contains 10 ml of 0.9% Sodium Chloride Injection BP.

Pharmacology:
Pantolok (Pantoprazole) is chemically a novel substituted benzimidazole derivative, which suppresses the final step in gastric acid production by forming a covalent bond to two sites of the H+/K+ - ATPase enzyme system at the secretory surface of the gastric parietal cell. This leads to inhibition of both basal and stimulated gastric acid secretion irrespective of the stimulus. The binding to the H+/K+ - ATPase results in duration of antisecretory effect that persists longer than 24 hours. Pantoprazole (Pantolok) is quantitatively absorbed and bioavailability does not change upon multiple dosing. Pantoprazole (Pantolok) is extensively metabolized in the liver. Almost 80% of an oral dose is excreted as metabolites in urine; the remainder is found in feces and originates from biliary secretion.

Dosage And Administration:
Delayed release tablet: The usual recommended adult oral dose is 40 mg is given once daily, before breakfast. The duration of therapy is ranging from 2-8 weeks. Duodenal ulcers: 40 mg once daily for 2 to 4 weeks. Gastric ulcers: 40 mg once daily for 4 to 8 weeks. Reflux esophagitis: 40 mg once daily for 4 to 8 weeks. In resistant ulcers: 40 mg once daily for 8 weeks. Ulcers induced by NSAIDs: 40 mg once daily, in patients receiving continuous treatment with NSAIDs. GI bleeding from stress or acid peptic diseases: 40 mg once daily, if required the dosage may be increased. Eradication of Helicobacter pylori: 40 mg twice daily in combination with appropriate antibiotic Zollinger-Ellison syndrome: 40 mg Four times daily. Once control of acid secretion has been achieved, the dose should be gradually reduced to the lowest effective dose that maintains acid control. Prophylaxis for acid aspiration syndrome during induction of anesthesia 40 mg 1 or 2 tablet should be given the evening before surgery and repeated again the morning of surgery.

Contraindications:
Pantoprazole is contraindicated in patients with known hypersensitivity to any component of the formulation.

Warning And Precaution:
Proton pump inhibitor should be used with caution in patients with liver diseases, in pregnancy and in breast-feeding. Proton pump inhibitors may mask symptoms of gastric cancer; particular care is required in those whose symptoms change and in those over 45 years of age; the presence of gastric malignancy should be excluded before treatment.

Side Effects:
Side effects of the Proton pump inhibitor include gastro-intestinal disturbances including diarrhea, nausea, vomiting, constipation, abdominal pain, blurred vision, depression and dry mouth.

Use in Pregnancy and Lactation:
There are no data on the excretion of Pantoprazole into the breast milk and also there are no

available data on administration of Pantoprazole to pregnant women. A decision should be made whether to discontinue the drug, taking into account the benefit of the drug to the mother.

Drug Interaction:
Pantoprazole is metabolized through the cytochrome P-450 system, and subsequently undergoes Phase II conjugation. Based on studies evaluating possible interactions of Pantoprazole with other drugs metabolized by the cytochrome P-450 system, no dosage adjustment is needed with concomitant use of the following drugs; theophylline, antipyrine, caffeine, carbamazepine, diazepam, diclofenac, digoxin, ethanol, glyburide, oral contraceptive (Levonorgestrel / ethinyl estradiol), metoprolol, nifedipine, phenytoin, or warfarin. There was also no interaction with concomitanty administered of antacids.

Overdosage:
There are no known symptoms of overdosage in humans. Since Pantoprazole is highly protein bound, it is not readily dialyzable. Apart from symptomatic and supportive management, no specific therapy is recommended.

Storage:
Keep below 30°C temperature, away from light & moisture. Keep out of the reach of children.

Packing:
Pantolok 20 tablet: Each box contains 100 (10x10's) tablets in Alu-Alu blister strips. Pantolok 40 tablet: Each box contains 50 (5x10's) tablets in Alu-Alu blister strips. Pantolok 40 IV injection: Each box contains one vial of 40 mg Pantoprazole, one ampoule of 10 ml of 0.9% Sodium Chloride Injection and one sterile disposable syringe (10 ml).

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.