Pantoflux 20

Pantoprazole USP 20mg

Composition:
Pantoflux 20 Tablet : Each enteric coated tablet contains Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 20 mg.

Pharmacology:
Pantoprazole is a proton pump inhibitor (PPI) that suppresses the final step in gastric acid production by covalently binding to the (H+, K+)-ATPase enzyme system at the secretory surface of the gastric parietal cell. This effect leads to inhibition of both basal and stimulated gastric acid secretion, irrespective of the stimulus. The binding to the (H+, K+)-ATPase results in a duration of antisecretory effect that persists longer than 24 hours for all doses tested (20 mg to 120 mg).

Indications:
Pantoprazole (Pantoflux 20) is indicated where suppression of acid secretion is of therapeutic benefit. Pantoprazole (Pantoflux 20) is registered for the following indications: -

1. Peptic ulcer diseases (PUD)
2. Gastro esophageal reflux diseases (GERD)
3. Treatment of ulcer resistant to H2 receptor antagonists (H2RAs)
4. Treatment of ulcers induced by non-steroidal anti-inflammatory drugs (NSAIDs)
5. Gastrointestinal (GI) bleeding from stress or acid peptic diseases
6. Eradication of Helicobacter pylori (in combination with antibiotics)
7. Zollinger-Ellison syndrome
8. Prophylaxis for acid aspiration syndrome during induction of anesthesia

Dosage and administration:
The usual starting dose is 40 mg once daily & maintenance dose is 20 mg once daily to be taken 30 minutes before breakfast. Duodenal ulcer : 40 mg daily in the morning for two weeks, continued for further two weeks if not fully healed. Gastric ulcer : 40 mg daily in the morning for four weeks, continued for further four weeks if not fully healed. Gastro-esophageal reflux disease : 40 mg daily in the morning for four weeks, continued for further four weeks if not fully healed; may be continued at 20 mg daily (long-term management), increased to 40 mg daily if symptoms return. Duodenal ulcer associated with Helicobacter pylori : 40 mg twice daily associated with appropriate antibiotic regimen. Ulcer induced by non-steroidal anti-inflammatory drugs (NSAIDs): Pantoprazole 40 mg daily in the morning has been used to prevent the formation of gastro duodenal lesions in patients receiving continuous treatment with NSAIDs. Gastro-intestinal bleeding from stress or acid peptic diseases : The usual adult oral dose is 40 mg once daily, preferably in the morning with or without food, if required dose may be increased

Side Effects:
Side effects of the proton pump inhibitors include gastro-intestinal disturbances (including diarrhoea, nausea and vomiting, constipation, flatulence, abdominal pain), headache hypersensitivity reactions (including rash, urticaria, angioedema, bronchospasm), pruritus, dizziness, peripheral edema, muscle and joint pain, malaise, blurred vision, depression and dry mouth.

Contraindications:
Pantoprazole Sodium enteric coated tablet is contraindicated in patients with known hypersensitivity to any component of the formulation or any substituted benzimidazole.

Warning and Precautions:
Proton pump inhibitors should be used with caution in patients with liver disease, in pregnancy and breast feeding, before treatment the presence of gastric malignancy should be excluded. No problem with Pantoprazole has been encountered in clinical use in elderly patients. No dosage adjustment of Pantoprazole is required in patients with renal impairment but prolongation of metabolism leading to a slight rise in peak plasma levels occurs in hepatic cirrhosis and it is recommended that the dosing is reduced to every other day.

Drug Interaction:
Pantoprazole does not react with the cytochrome P-450 system. No drug interaction has been reported in a large series of studies examining reactions with contraceptives, diazepam. diclofenac, ethanol, caffeine, metoprolol, theophylline, digoxin, phenytoin, nifedipine and warfarin.

Use in special Populations:
Pregnancy: Pregnancy Category B
Reproduction studies have been performed in rats at oral doses up to 88 times the recommended human dose and in rabbits at oral doses up to 16 times the recommended human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Pantoprazole. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers:
Pantoprazole and its metabolites are excreted in the milk of rats. Pantoprazole excretion in human milk has been detected in a study of a single nursing mother after a single 40 mg oral dose. The clinical relevance of this finding is not known. Many drugs which are excreted in human milk have a potential for serious adverse reactions in nursing infants. Based on the potential for tumorigenicity shown for Pantoprazole in rodent carcinogenicity studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

Overdose Effects:
Experience in patients taking very high doses of Pantoprazole (> 240 mg) is limited. Spontaneous post-marketing reports of overdose are generally within the known safety profile of Pantoprazole. Pantoprazole is not removed by hemodialysis. In case of overdosage, treatment should be symptomatic and supportive.

Storage Conditions:
Store below 30°C temperature, dry place and away from light. Keep all medicine out of the reach of children.

Packing: 10x10's Tablets in Alu- Alu Blister packs.

Manufactured by:
GUARDIAN
Healthcare Ltd.
Amtola, Zirabo, Ashulia
Dhaka, Bangladesh.