Pantosil®

Pantoprazole 20 mg

Presentation
Pantosil® 20: Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate INN equivalent to Pantoprazole 20 mg.
Pantosil® 40: Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate INN equivalent to Pantoprazole 40 mg.

Description
Pantoprazole (Pantosil®) 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 (Pantosil®) is quantitatively absorbed and bioavailability does not change upon multiple dosing. Pantoprazole (Pantosil®) 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.

Indications
Pantoprazole (Pantosil®) is indicated where suppression of acid secretion is of therapeutic benefit. Pantoprazole (Pantosil®) is registered for the following indications:
1. Gastro esophageal reflux diseases (GERD)
2. Peptic ulcer diseases (PUD)
3. Gastrointestinal (GI) bleeding from stress or acid peptic diseases
4. Eradication of Helicobacter pylori (in combination with antibiotics)
5. Treatment of ulcers induced by non-steroidal anti-inflammatory drugs (NSAIDs)
6. Treatment of ulcer resistant to H_2 receptor antagonists (H_2RAs)
7. Prophylaxis for acid aspiration syndrome during induction of anaesthesia
8. Zollinger-Ellison syndrome

Dosage And Administration
Pantosil® delayed release tablets are available for oral administration only. The usual recommended adult oral dose is 40 mg given once daily, preferably in the morning with or without food. The duration of therapy is ranging from 2-8 weeks. Duodenal Ulcers: Pantosil® 40 mg tablet, once daily for 2 to 4 weeks. Duodenal ulcer generally heals within 2 weeks. Gastric ulcers: Pantosil® 40 mg tablet, once daily for 4 to 8 weeks. Gastric ulcer generally heals within 4 weeks. Reflux esophagitis: Pantosil® 40 mg tablet, once daily for 4 to 8 weeks. Reflux esophagitis generally heals within 4 weeks of treatment. In resistant ulcers: Pantosil® 40 mg tablet, once daily for 8 weeks. Ulcers induced by NSAIDs: Pantosil® 40 mg tablet once daily, in patients receiving continuous treatment with NSAIDs. GI bleeding from stress or acid peptic diseases: Usual adult oral dosage, if required the dosage may be increased. Eradication of Helicobacter pylori: Triple therapy of Pantosil®40 mg twice daily in combination with appropriate antibiotic for one week achieved eradication rates of 90 to100%. Zollinger-Ellison syndrome: 4 Pantosil® 40 mg tablets per day. 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 anaesthesia: 1 or 2 Pantosil® 40 mg tablet should be given the evening before surgery and repeated again the morning of surgery. Maintenance therapy: Maintenance treatment should involve the lowest dose of the drug. Both 20 and 40 mg doses of Pantoprazole (Pantosil®) are safe and effective in maintaining patients with healed reflux esophagitis and PUD in remission.

Adverse Effects
Potentially life-threatening effects: None has been reported with respect to Pantoprazole. Severe or irreversible adverse effects: No serious adverse reactions have been described to date. Symptomatic adverse effects: Headache (1.3%) and diarrhoea (1.5%) are the two commonest reported adverse events. Peripheral edema has occasionally been reported in female patients. Other side effects may include abdominal pain, dizziness, nausea, epigastric discomfort, flatulence, skin rash, pruritus etc.

Contraindications
Pantosil® delayed release tablets are contraindicated in patients with known hypersensitivity to any components of the formulation.

Precautions
Patients should be cautioned that Pantosil® delayed release tablets should not be split, chewed or crushed.

Use in pregnancy & lactation
Lactating mother: There are no data on the excretion of Pantoprazole into the breast milk. 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.
Pregnant women: No data are available on administration of Pantoprazole to pregnant women. However this drug should be used during pregnancy, only if clearly needed.
Neonates and children: No data are available on administration of Pantoprazole to neonates and children.
The elderly: No problems with Pantoprazole have been encountered in clinical use in this patient group.
Concurrent disease: No dosage adjustment of Pantoprazole is required in patients with mild, moderate or severe renal insufficiency or in elderly patients. No dosage adjustment is necessary in patients undergoing haemodialysis. No dosage adjustment is needed in patients with mild or moderate hepatic impairment. In hepatic cirrhosis, it is recommended that the dosing is reduced to every other day.

Drug Interaction
No dosage adjustment is needed with concomitant use of the following drugs; theophylline, antipyrine, caffeine, carbamazepine, diazepam, diclofenac, digoxin, ethanol, glyburide, an oral contraceptive (Levonorgestrel/ethinyl estradiol), metoprolol, nifedipine, phenytoin or warfarin. There was also no interaction with concomitantly administered antacids and food.

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.

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

Commercial Pack
Pantosil® 20: Each box contains 5 Alu-Alu blister strips of 10 tablets.
Pantosil® 40: Each box contains 5 Alu-Alu blister strips of 10 tablets.

Manufactured by :
Silva
Pharmaceuticals Limited
Maijdee, Noakhali, Bangladesh