Pantohil

Pantoprazole USP

Composition
Pantohil 20 Tablet: Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 20 mg.
Pantohil 40 Tablet: Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 40 mg.

Description
Pantoprazole (Pantohil) 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 Ht/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 Htik- ATPase results in duration of antisecretory effect that persists longer than 24 hours. Pantoprazole (Pantohil) is quantitatively absorbed and bioavailability does not change upon multiple dosing. Pantoprazole (Pantohil) 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 and Usage
Pantoprazole (Pantohil) is indicated where suppression of acid secretion is of therapeutic benefit. Pantoprazole (Pantohil) 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 anaesthesia Dosage and Administration Delayed release tablet The usual recommended adult oral dose is 40 mg given once daily, before breakfast. The duration of therapy is ranging from 2-8 weeks. Duodenal Ulcers: Pantohil 40 mg tablet, once daily for 2 to 4 weeks. Duodenal ulcer generally heals within 2 weeks. Gastric ulcers: Pantohil 40 mg tablet, once daily for 4 to 8 weeks. Gastric ulcer generally heals within 4 weeks. Reflux esophagitis: Pantohil 40 mg tablet, once daily for 4 to 8 weeks. Reflux esophagitis generally heals within 4 weeks of treatment. In resistant ulcers: Pantohil 40 mg tablet, once daily for 8 weeks. Ulcers induced by NSAIDs: Pantohil 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 Pantohil 40 mg twice daily in combination with appropriate antibiotic for one week achieved eradication rates of 90 to 100%. Zollinger-Ellison syndrome: 4 Pantohil 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 Pantohil 40 mg tablet should be given the evening before surgery and repeated again the morning of surgery.
Injection,

Duodenal ulcer, gastric ulcer, gastrointestinal lesions refractory to H_2 blockers, Zollinger-Ellison syndrome	40 mg per day intravenously
Reflux esophagitis	20-40 mg per day intravenously

Intravenous Pantoprazole should be replaced with oral therapy as soon as possible.

Preparation for Use
A ready-to-use solution is prepared by injecting 10 ml 0.9% Sodium Chloride Intravenous Infusion into the vial containing the dry powder. The resulting solution should be used within 12 hours and stored at 2-8°C. After preparation, the solution should be administered over 2 to 15 minutes.

Maintenance Therapy
Maintenance treatment should involve the lowest dose of the drug. Both 20 and 40 mg doses of Pantoprazole (Pantohil) are safe and effective in maintaining patients with healed reflux esophagitis and PUD in remission.

Contraindication
Pantohil delayed release tablets are contraindicated in patients with known hypersensitivity to any of the formulation.

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

Side 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. It doesn't influence renal, cardiovascular, respiratory, endocrine, cognitive or motor functions and no consistent change have been found in any biochemical or haematological parameters. 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.

Pregnancy & Lactation
Pregnant women: Available studies have not found any risk to the fetus. *Lactating mother:* There are no data on the excretion of Pantoprazole into the breast milk.

Neonates & Children
No data are available on administration of Pantoprazole.

Elder Patient
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 Interactions
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 cytochoreme P-450 system, 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, phenytion, or warfarin. There was also no interaction with concomitantly administered 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
Do not store above 30° C. Keep away from light and out of the reach of children.

Packing
Pantohil 20 Tablet: Each pack contains 20 tablets in Alu-Alu blister pack.
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Goodman
Manufactured by:
Goodman Pharmaceuticals Ltd.
Better Health For All
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