Panpro

Pantoprazole

Composition

Panpro 20 mg tablet: Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 20 mg.

Panpro 40 mg tablet: Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 40 mg.

Panpro 40 mg IV injection: Each vial contains sterile Pantoprazole Sodium BP equivalent to Pantoprazole 40 mg.

Description: 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.

Indications and Usage

Pantoprazole (**Panpro**) is indicated where suppression of acid secretion is of therapeutic benefit. **Panpro tablet** is registered for the following indications: -

1. Peptic ulcer diseases (PUD), 2. Gastro esophageal reflux diseases (GERD), 3. Treatment of ulcer resistant to H_2 receptor antagonists, 4. Treatment of ulcer 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: ***Panpro tablets***

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 Ulcer: **Panpro** 40 mg tablet, once daily for 2 to 4 weeks. Duodenal ulcer generally heals within 2 weeks.

Gastric ulcer: **Panpro** 40 mg tablet, once daily for 4 to 8 weeks. Gastric ulcer generally heals within 4 weeks.

Reflux esophagitis: **Panpro** 40 mg tablet, once daily for 4 to 8 weeks. Reflux esophagitis generally heals within 4 weeks of treatment. In resistant ulcer: **Panpro** 40 mg tablet, once daily for 8 weeks.

Ulcer induced by NSAIDs: **Panpro** 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 **Panpro** 40 mg twice daily in combination with appropriate antibiotic for one week achieved eradication rates of 90 to100%. Zollinger-Ellison syndrome: 4 **Panpro** 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 anesthesia: 1 or 2 **Panpro** 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 are safe and effective in maintaining patients with healed reflux esophagitis and PUD in remission.

	Conditions	Dose & Frequency
Panpro 40 mg IV injection	Usual adult dose	40 mg once daily
	Duodenal ulcer	40 mg once daily, 2- 4 weeks
	Gastric ulcer	40 mg once daily, 4- 8 weeks
	Gastro esophageal reflux disease	40 mg once daily, 4 weeks

Panpro 40mg IV injection:

Method of administration: Panpro 40 mg IV injection should be given as slow intravenous injection. The solution for IV injection is obtained by adding to the vial 10 ml of the solvent provided. After reconstitution, the injection should be given slowly over a period of at least 2.5 minutes at a maximum rate of 4 ml per minute.

Infusion: For IV infusion reconstitute one sterile single dose vial of Panpro IV injection with 10 ml of sterile WFI in ampoule to make 10 ml solution containing 4 mg/ml of pantoprazole approximately. Subsequently add 10 ml of reconstituted solution containing 4 mg/ml of omeprazole approximately, to 90 ml 0.9% sodium chloride solution to make 100 ml solution of 0.4 mg/ml of pantoprazole approximately. The resultant infusion should be given intravenously over a period of 2 - 15 minutes. Do not dilute to <0.4 mg/ml. Reconstitute solution and further diluted solution is stable for 6 hours only. Do not mix with other drugs/ solutions.

Contra-indication: Panpro tablets are contraindicated in patients with known hypersensitivity to any of the formulation.

Precautions: Patients should be cautioned that **Panpro 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 diarrhea (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.

Drug Interactions: Pantoprazole is metabolized through the cytochrome P-450 system, and subsequently undergoes phase-2 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, phenytoin, 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.

Commercial Pack:

Panpro 20 mg tablet: Each box contains 10 Alu-Alu blister packs of 10 tablets.

Panpro 40 mg tablet: Each box contains 5 Alu-Alu blister packs of 10 tablets.

Panpro 40 mg IV injection: Each combipack contains 1 vial of 40 mg Pantoprazole and one ampoule of 10 ml water for injection or 10 ml sterile 0.9% sodium chloride BP injection.

Panpro 40 mg IV injection is manufactured by Popular Pharmaceuticals Ltd. for

Manufactured by
BIOPHARMA LIMITED
A-116, BSCIC Industrial Estate
Tongi, Gazipur, Bangladesh

For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.