Protocid

Tablet & Injection

Pantoprazole

Composition

Protocid 20 Tablet: Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate BP equivalent to Pantoprazole 20 mg.

Protocid 40 Tablet: Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate BP equivalent to Pantoprazole 40 mg.

Protocid IV Injection: Each vial contains lyophilized powder of Pantoprazole Sodium Sesquihydrate BP equivalent to 40 mg Pantoprazole.

Pharmacology

Pantoprazole is a substituted benzimidazole, which inhibits the secretion of hydrochloric acid in the stomach by specific action on the proton pumps of the parietal cells. Pantoprazole is converted to its active form in the acidic canaliculi of the parietal cells & it inhibits the H^+/K^+ ATPase enzyme, i.e. the final stage in the production of hydrochloric acid in the stomach. The inhibition is dose-dependent and affects both basal and stimulated acid secretion. Pantoprazole is rapidly absorbed and the maximal plasma concentration is achieved even after a single oral dose. Serum protein binding of Pantoprazole is about 98%. The substance is almost exclusively metabolized in the liver and about 80% is eliminated through urine as metabolites, the rest are excreted with the faeces.

Indications

For the prevention and treatment of benign gastric ulcer, duodenal ulcer, NSAID associated complications, peptic ulcer associated with *Helicobacter pylori*, Erosive esophagitis, Zollinger-Ellison Syndrome, Prophylaxis for acid aspiration syndrome during induction of anaesthesia or due to stress.

Dosage and Administration

Dosage form	Conditions	Dose	Frequency	Duration
Tablet 20 mg and 40 mg	Benign gastric ulcer	40 mg	Once daily	4-8 weeks
	Duodenal ulcer	40 mg	Once daily	2-4 weeks
	Erosive esophagitis	20–40 mg	Once daily	4-8 weeks
	Maintenance of healing of Erosive esophagitis	20 mg increased to 40 mg, if symptoms return	Once daily	---
	NSAIDs induced ulcer.	20 mg	Once daily	----
	Prophylaxis for acid aspiration syndrome during induction of anaesthesia or due to stress	20 mg	At the evening before surgery and repeated again in the morning of surgery	----
	Zollinger-Ellison Syndrome	Initially 80 mg adjusted according to response (Elderly max. 40 mg daily); daily dose above 80 mg given in 2 divided doses	Once daily	Up to control of acid secretion

Dosage form	Conditions	Dose	Frequency	Duration
IV injection	Gastric ulcer	40 mg	Once daily	until oral administration can be resumed
	Duodenal ulcer	40 mg	Once daily	until oral administration can be resumed
	GERD	40 mg	Once daily	until oral administration can be resumed
	Zollinger–Ellison syndrome and other hypersecretory conditions	initially 80 mg then 160 mg if rapid acid control required	once daily adjusted according to response; daily doses above 80 mg given in 2 divided doses	until oral administration can be resumed

Mode of administration

Injection: The 4 mg / ml solution for IV injection is obtained by adding 10 ml of the provided solvent to the vial containing 40 mg Pantoprazole lyophilized powder. 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 lyophilized single dose vial of **Protocid** IV injection with 10 ml of provided solvent to make 10 ml solution containing 4 mg/ml of Pantoprazole approximately.

Dilute the reconstituted solution to make final 100 ml solution of 0.4 mg/ml (approximately) of Pantoprazole with 0.9% Sodium Chloride Solution or 5% dextrose solution. The resultant infusion solution should be given intravenously over a period of 15 minutes. Do not dilute the Pantoprazole solution to < 0.4 mg/ml.

Both the reconstituted solution must be used within 24 hours from the time of initial reconstitution if stored at room temperature. Treatment with **Protocid** IV infusion should be discontinued as soon as the patient can be treated with **Protocid** Delayed-Release Tablets.

Peptic ulcer associated with Helicobacter pylori:

Regimen	Duration
Pantoprazole (**Protocid**) 40 mg twice daily. Amoxicillin (Moxilin) 1 g twice daily. Clarithromycin (Claricin) 500 mg twice daily.	01-02 weeks
Pantoprazole (**Protocid**) 40 mg twice daily. Clarithromycin (Claricin) 250 mg twice daily. Metronidazole (Dirozyl) 400 mg twice daily.	01 week
Pantoprazole (**Protocid**) 40 mg twice daily. Amoxicillin (Moxilin) 1 g twice daily. Metronidazole (Dirozyl) 400 mg twice daily.	01-02 weeks

Pediatric Use : Safety and effectiveness of Pantoprazole in neonates and children have not been established.

Elderly : Dose adjustment is not required in the elderly.

Impaired Renal Function: The daily dose of 20 mg or 40 mg can be given.

Impaired Liver Function: In patients with severe liver disease dose should not be more than 20 mg Pantoprazole per day.

OR AS DIRECTED BY THE PHYSICIAN.

Contraindication

Contraindicated in patients with known hypersensitivity to Pantoprazole or any component of the product.

Precaution

Use in Pregnancy

Pregnancy Category is B. This drug should be used during pregnancy only if clearly needed.

Use in Lactation

There is no information about the safety of Pantoprazole during breast feeding in human. It should only be used during nursing if considered essential.

Side Effects

Pantoprazole is generally well tolerated and no life threatening or severe effects have been reported. Most commonly occurred side effects are nausea, vomiting, headache, diarrhea, flatulence, abdominal pain and skin rash. In short-term and long-term trials, the following events occurred at a rate of ≥ 1% in Pantoprazole treated patients: insomnia, hyperglycemia, injection site reaction (including thrombophlebitis and abscess), anxiety, arthralgia, asthenia, back pain, bronchitis, chest pain, constipation, cough, dizziness, dyspepsia, flu syndrome, gastroenteritis, hyperlipemia, abnormal liver function tests, migraine, neck pain, rectal disorder, rhinitis, sinusitis, upper respiratory tract infection, increased urinary frequency and urinary tract infection. It does not influence renal, cardiovascular, respiratory, endocrine, cognitive or motor function. Peripheral edema has occasionally been reported in female patients.

Drug Interactions

No clinically relevant drug interactions have been reported so far. 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, Naproxen, Digoxin, Ethanol, Oral Contraceptive, Metoprolol, Nifedipine, Phenytoin, Warfarin, Metronidazole, Amoxicillin and Erythromycin.

Overdosage

Experience in patients taking very high doses of Pantoprazole is limited. There have been reports of patients taking 400 to 600 mg Pantoprazole with no adverse effects. In the cases of overdosage with clinical signs of intoxication, the usual rules of intoxication therapy are applied.

Storage

Store below 30^0 C temperature & dry place, protected from light.
Keep all medicines out of reach of children.

Supply

Protocid 20 mg Tablet: Each box contains 10×14 Tablets in alu-alu blister strips.

Protocid 40 mg Tablet: Each box contains 5×10 Tablets in alu-alu blister strips.

Protocid IV Injection : Each box contains 1 vial of lyophilized Pantoprazole 40 mg and 1 ampoule of 10 ml 0.9% Sodium chloride injection in blister strip and a 10 ml sterile disposable syringe.

** Further information is available on request.*

Manufactured by:
The ACME Laboratories Ltd.
Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness
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