Pantoprazole

PANTOPRON
40mg Enteric-Coated Tablet

Proton Pump Inhibitor

FORMULATION:
Each enteric-coated tablet contains:
Pantoprazole (as sodium sesquihydrate) ..... 45.1 mg

INDICATIONS:
Pantoprazole is proton pump inhibitor with actions and uses similar to those of omeprazole. It is given as sodium salt but doses are expressed in terms of the base. Pantoprazole sodium 11.28 mg is equivalent to about 10 mg of pantoprazole. Once-daily doses should be taken in the morning in the treatment of:

- Gastro-oesophageal reflux disease
- Peptic ulcer disease
- Prophylaxis for NSAID-associated ulceration
- In the treatment of pathological hypersecretory states such as the Zollinger-Ellison syndrome.

PHARMACOKINETICS:
Pantoprazole is rapidly absorbed and peak plasma concentrations are achieved about 2 to 2.5 hours after an oral dose. The oral bioavailability is about 77% with enteric-coated tablet formulation, and does not vary after single or multiple doses. Pantoprazole is about 98% bound to plasma proteins. It is extensively metabolised in the liver, primarily by cytochrome P450 isoenzyme CYP2C19, to demethylpantoprazole; small amounts are also metabolised by CYP3A4, CYP2D6, and CYP2C9. Metabolites are excreted mainly (about 80%) in the urine, with the remainder being excreted in faeces via the bile. The terminal elimination half-life is about 1 hour, and is prolonged in hepatic impairment; the half-life in patients with cirrhosis is 3 to 6 hours. Although the elimination half-life has been reported to be 3.5 to 10 hours in slow metabolisers, minimal accumulation occurs with once daily dosing.

DOSAGE & ADMINISTRATION:
In the treatment of gastro-oesophageal reflux disease, the usual oral dose is 20 to 40 mg once daily for 4 weeks, increased to 8 weeks if necessary. For maintenance therapy, treatment can be continued with 20 to 40 mg daily. Alternatively, for recurring symptoms, an on-demand regimen of 20 mg daily may be given.

The usual dose for the treatment of peptic ulcer disease is 40 mg once daily. Treatment is usually given for 2 to 4 weeks for duodenal ulceration, or 4 to 8 weeks for benign gastric ulceration. For the eradication of Helicobacter pylori, pantoprazole may be combined with two antibacterial medications in a 1-week triple therapy regimen. Effective regimens include: pantoprazole 40 mg twice daily combined with clarithromycin 500 mg twice daily and amoxicillin 1 g twice daily, or combined with clarithromycin 500 mg twice daily and amoxicillin 1 g twice daily, or combined with clarithromycin 250 mg twice daily and metronidazole 400 mg twice daily.

Patients who require prophylaxis for NSAID-associated ulceration may take 20 mg daily.

In the treatment of pathological hypersecretory states such as the Zollinger-Ellison syndrome, the initial dose is 80 mg daily, adjusted as required. Doses of up to 240 mg daily have been used. Daily doses greater than 80 mg should be given in 2 divided doses.

ADVERSE EFFECTS & PRECAUTIONS:
Dosage may need to be reduced in severe hepatic impairment. Liver function should be monitored regularly. Therapy should be stopped if liver enzymes are elevated.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY:
Pantopron 40 mg enteric-coated tablet (box of 30's)

STORE AT TEMPERATURES NOT EXCEEDING 30ºC.

Pharma
Nutria

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