Pantium™

Pantoprazole Sodium Sesquihydrate BP

Jenphar Bangladesh | جنفار بنغلاديش

Composition:

Pantium™ 20 Tablet: Each delayed release tablet contains Pantoprazole sodium sesquihydrate BP equivalent to Pantoprazole 20 mg.

Pantium™ 40 Tablet: Each delayed release tablet contains Pantoprazole sodium sesquihydrate BP equivalent to Pantoprazole 40 mg.

Pharmacology:

Pantoprazole, a substituted benzimidazole, is an inhibitor of gastric acid secretion. Pantoprazole inhibits secretion of gastric acid by blocking the hydrogen-potassium-adenosine triphosphatase enzyme system, the so called 'Proton Pump' of the gastric parietal cell. Absorption of Pantoprazole begins only after the tablet leaves the stomach. Peak serum concentration (Cmax) and area under the serum concentration time curve (AUC) increase in a manner proportional to oral dose from 10 mg to 80 mg. Pantoprazole does not accumulate and its pharmacokinetics are unaltered with multiple daily dosing. Following oral administration, the serum concentration of pantoprazole declines biexponentially with a terminal elimination half life of approximately one hour. The absorption of pantoprazole is rapid, with a Cmax of 2.5 µg/mL that occurs approximately 2.5 hours after single or multiple oral 40-mg doses. Pantoprazole is well absorbed; it undergoes little first-pass metabolism resulting in an absolute bioavailability of approximately 77%. Administration of pantoprazole with food may delay its absorption up to 2 hours or longer; however, the Cmax and the extent of pantoprazole absorption (AUC) are not altered. Thus, pantoprazole may be taken without regard to timing of meals. The serum protein binding of pantoprazole is about 98%, primarily to albumin. Pantoprazole is extensively metabolized in the liver through the cytochrome P450 (CYP) system. After a single oral dose of 14C-labeled pantoprazole to healthy, normal metabolizer volunteers, approximately 71% of the dose was excreted in the urine with 18% excreted in the feces through biliary excretion. There was no renal excretion of unchanged pantoprazole.

Indications:

Benign gastric ulcer, duodenal ulcer, Gastro-esophageal reflux disease (GERD), NSAID induced peptic ulcer, acid hypersecretory conditions including Zollinger-Ellison syndrome, eradication of Helicobacter pylori (in combination with Antibiotics), ulcer resistant to H2-receptor antagonists.

Dose and administration:

Benign gastric ulcer: 40 mg daily in the morning for 4 weeks, continued for further 4 weeks if not fully healed. Duodenal ulcer: 40 mg daily in the morning for 2 weeks, continued for further 2 weeks if not fully healed. GERD: 20-40 mg daily in the morning for 4 weeks, continued for further 4 weeks if not fully healed. NSAIDs induced peptic ulcer: 20 mg daily. Acid hypersecretory conditions including Zollinger-Ellison syndrome: Initially 80 mg once daily adjusted according to response (Elderly - max. 40 mg daily), daily doses above 80 mg given in two divided doses. Eradication of Helicobacter pylori: 40 mg twice daily by triple therapy with antibiotics. Ulcer resistant to H2-receptor antagonists: 40 mg once daily for 8 weeks. Maintenance therapy: 20 mg daily, increased to 40 mg daily if symptoms return.

Safety and effectiveness in case of children have not been established.

Contra-indication:

Pantoprazole is contraindicated in patients with known hypersensitivity to the active drug or any other components of the formulation.

Warning & precautions:

Patients should be cautioned that this tablet should not be split, crushed or chewed.

The tablet should be swallowed whole, with or without food in the stomach. Concomitant administration of antacids does not affect the absorption of Pantoprazole.

Side effects:

Common: Pantoprazole is well tolerated in both short term and long term treatment. Headache and diarrhoea are the most common side effects.

Rare: Abdominal pain, flatulence, rash, insomnia, hyperglycemia.

Use in pregnancy & lactation:

Teratology studies have been performed in animals and have revealed no evidence of impaired fertility or harm to the fetus due to pantoprazole. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Pantoprazole excretion in human milk has been detected in a study of a single nursing mother after a single 40 mg oral dose. The clinical relevance of this finding is not known. 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.

Drug interactions:

Pantoprazole is metabolized through the cytochrome P450 system, primarily the CYP2C19 and CYP3A4 isozymes, and subsequently undergoes Phase II conjugation. Based on studies evaluating possible interactions of pantoprazole with other drugs, no dosage adjustment is needed with concomitant use of the following: theophylline, cisapride, antipyrine, caffeine, carbamazepine, diazepam (and its active metabolite,desmethyldiazepam),diclofenac, naproxen, piroxicam, digoxin, ethanol, glyburide, an oral contraceptive (levonorgestrel/ethinyl estradiol), metoprolol, nifedipine, phenytoin, warfarin (see below), midazolam, clarithromycin, metronidazole, or amoxicillin. Because of profound and long lasting inhibition of gastric acid secretion, pantoprazole may interfere with absorption of drugs where gastric pH is an important determinant of their bioavailability (eg, ketoconazole, ampicillin esters, and iron salts).

Storage:

Keep out of the reach of children. Store in a cool and dry place below 30°C, protect from light & moisture.

Packing:

Pantium™ 20 Tablet: Each box contains 60 tablets in Alu-Alu blister packs.

Pantium™ 40 Tablet: Each box contains 30 tablets in Alu-Alu blister packs.

TM = Trade Mark

Manufactured by:
Jenphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh

Ver.: 02
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