

Pantex[®]

Pantoprazole

Description

Pantex[®] is a preparation of Pantoprazole. It is a substituted benzimidazole derivative that suppresses the proton pump, final step of gastric acid secretion, by forming a covalent bond to two sites of H⁺-K⁺ ATPase enzyme. This leads to inhibition of both basal and stimulated gastric acid secretion irrespective to the stimulus. The binding of Pantex[®] to the H⁺-K⁺ ATPase results antisecretory effect which persist longer than 24 hours.

Indications

Pantex[®] is indicated in the following indications:

- Peptic ulcer diseases
- Gastro esophageal reflux diseases
- Treatment of ulcer resistant to H₂-receptor antagonist
- Treatment of ulcer induced by NSAIDs
- Gastro intestinal bleeding from stress or acid peptic diseases
- Eradication of Helicobacter pylori (in combination with antibiotics)
- Zollinger-Ellison syndrome
- Prophylaxis for acid aspiration syndrome during induction of anesthesia

Dose and Administration

The usual recommended adult dose of Pantex[®] enteric coated tablet is 40mg given once daily, Preferably in the morning with or without food. The duration of therapy is ranging from 2-8weeks.

Duodenal ulcer: Pantex[®] 40mg tablet once daily for 2-4 weeks.

Gastric ulcer: Pantex[®] 40mg tablet once daily for 4-8 weeks.

Reflux esophagitis: Pantex[®] 40mg tablet for once daily for 4-8 weeks.

Resistance ulcer: Pantex[®] 40mg tablet once daily for 8 weeks.

NSAIDs induced ulcer: Pantex[®] 40mg tablet once daily, in patients of continuous treatment with NSAIDs.

GI bleeding form stress or acid peptic diseases: Usual adult oral dosage, if required the dosage may be increased.

Eradication of Helicobacter pylori : Triple therapy of Pantex[®] 40mg tablet twice daily in combination with appropriate antibiotic for one week to achieve eradication rate of 90-100%

Zollinzer-Ellison syndrome: Four Pantex[®] 40mg 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 of acid aspiration syndrome during induction of anaesthesia: one to two Pantex[®] 40mg tablet should be given in the evening before surgery and repeated again the in morning of surgery.

Maintenance therapy :

Maintenance treatment should be involved the lowest dose of the drug. Both 20 and 40mg dose of Pantex[®] are safe and effective in maintaining patients with healed reflux esophagitis and PUD in remission.

Use in Pregnancy and Lactation

No data are available on administration of Pantoprazole to pregnant women. However, this drug can be used during pregnancy only if clearly needed. There is no data on the excretion of Pantoprazole into the breast milk.

Warning

Patients should be cautioned that Pantex[®] enteric coated tablet should not split, chewed or crushed.

Side Effects

No potentially life threatening side-effects or serious adverse reactions has been reported. In some few cases headache, diarrhea, abdominal pain, nausea, dizziness, epigastric discomfort, flatulence, skin rash, pruritis have been reported.

Contraindications

Pantoprazole is contraindicated to those patients who have known hypersensitivity to any component of the formulation.

Drug Interactions

Pantoprazole is metabolized through the Cytochrome P450 system, and subsequently undergoes phase II conjugation. 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, digoxin, ethanol, glyburide, oral contraceptive (levonorgestrel or ethynyl estradiol), metoprolol, nifedipine, phenytoin, or warfarin. There was also no interaction with concomitantly administered antacids.

Pharmaceutical Precautions

Stored in a cool dry place, protect from light.

Presentation

Pantex[®] 20 : Light yellow colored, round, enteric coated tablet. Each delayed release tablet contains Pantoprazole 20 mg as Sodium Sesquihydrate INN.

Pantex[®] 40 : Green colored, round, enteric coated tablet. Each delayed release tablet contains Pantoprazole 40 mg as Sodium Sesquihydrate INN.

Packaging Quantities

Pantex[®] 20 : Carton of 50 tablets in Alu-Alu blister.

Pantex[®] 40 : Carton of 30 tablets in Alu-Alu blister.

® Registered Trade Mark



ACI Limited