Only for the use of Medical Professionals

Pantex®

Pantoprazole

Prescribing information:

Description

Pantex® is a preparation of Pantoprazole. Pantoprazole is a proton pump inhibitor, i.e. it inhibits specifically and dose-proportionally the gastric H+/K+-ATPase enzyme, which is responsible for acid secretion in the parietal cells of the stomach. The substance is a substituted benzimidazole, which accumulates, in the acidic environment of the parietal cells after absorption. There it is converted into the active form, a cyclic sulphenamide, which binds to the H+/K+-ATPase, thus inhibiting the proton pump and causing potent and long-lasting suppression of basal and stimulated gastric acid secretion. As Pantoprazole acts distally to the receptor level, it can inhibit gastric acid secretion irrespective of the nature of the stimulus (acetylcholine, histamine, and gastrin). The binding of Pantoprazole to the H+/K+-ATPase results antisecretory effect which persists longer than 24 hours. Pantoprazole is extensively metabolized in the liver. Almost 80% of an oral dose is found in urine; the remainder is found in feces and originates from biliary secretion.

Indications

Pantex®capsule is indicated in;

- Peptic ulcer diseases (e,g,, Duodenal ulcer & Gastric ulcer)
- Gastro esophageal reflux diseases - Treatment of ulcer resistant to H2-receptor antagonists
- 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

Pantex® IV Injection is indicated in:

- Duodenal ulcer, gastric ulcer, and gastro-esophageal reflux disease associated with a history of erosive esophagitis
- Zollinger-Ellison syndrome (and other hypersecretory conditions)

Dosage and administration:

Pantex® Capsule

Adults and adolescents 12 years of age and above:

The usual recommended adult dose of **Pantex®** capsule is 40mg once daily, preferably in the morning with or without food. The duration of therapy is ranging from 2-8 weeks.

Duodenal ulcer: 40mg capsule once daily for 2-4 weeks.

Gastric ulcer: 40mg capsule once daily for 4-8 weeks.

Reflux esophagitis: 40mg capsule once daily for 4-8 weeks.

Resistance ulcer: 40mg capsule once daily for 8 weeks.

NSAIDS induced ulcer: 4omg capsule once daily, in patients of continuous treatment with NSAIDs.

GI bleeding from stress or acid peptic diseases: 40mg once daily, if required the dosage may be increased.

Eradication of Helicobacter pylori: Triple therapy of **Pantex®** 40mg capsule twice daily in combination with approprlate antibiotic for one week to achieve eradication rate of 90-100%.

Zollinger Ellison syndrome: Four **Pantex®** 40mg capsule 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 anesthesia:

One to two **Pantex®** 40mg capsule should be given in the evening before surgery and repeated in the morning of surgery.

Maintenance therapy

Treatment should be started with the lowest dose of the drug, Both 20 and 40mg dose are safe and effective in maintaining patients with healed reflux esophagitis and PUD in remission.

Elderly: No dose adjustment is necessary in the elderly for Pantoprazole capsule, However, in case of capsule the daily dose of 40 mg Pantoprazole should not be exceeded. An exception is combination therapy for eradication of H. pylori, where elderly patients should receive the usual Pantoprazole dose (2 x 40 mg/day) during 1 week treatment.

Children: Pantoprazole capsule is not recommended for use in children below 12 years of age.

Patients with hepatic impairment: In patients with severe hepatic impairment, the daily dose should be reduced to 20 mg Pantoprazole per day.

Patients with renal impairment: No dose adjustment is necessary for capsule in patients with renal impairment.

Pantex® IV Injection:

Adult over 18 years of age:

Duodenal ulcer, gastric ulcer, and gastro-esophageal reflux disease associated with a history of erosive esophagitis: The recommended adult dose is 40 mg **Pantex®** IV once daily by intravenous infusion for 7 to 10 days. Safety and efficacy of **Pantex®** IV for Injection as a treatment of patients with GERD and a history of erosive esophagitis for more than 10 days have not been demonstrated.

Zollinger-Ellison syndrome (and other hypersecretory conditions): Initially 80 mg (160 mg if rapid acid control required) then 80 mg once daily adjusted according to response; daily dosage above 80 mg should be given in 2 divided doses. Transition from **Pantex®** Injection to the oral formulation of **Pantex®** should be performed as soon as it is clinically justified.

Elderly:

No dose adjustment is necessary in the elderly for Pantoprazole IV injection.

Children:

The safety and effectiveness of Pantoprazole IV Injection is not recommended for use in patients below 18 years of age.

Patients with hepatic impairment: No dose adjustment is necessary for IV injection in patients with hepatic impairment.

Patients with renal impairment: No dose adjustment is necessary for IV injection in patients with renal impairment.

Method of administration:

Injection: Pantex® IV Injection should be administered intravenously over a period of at least 2 minutes. The solution for IV injection should be reconstituted with 10 ml of water for injection, to a final concentration of approximately 4 mg/ml. The reconstituted solution may be stored for up to 24 hours at room temperature prior to intravenous infusion and does not need to be protected from light.

Infusion: Pantex® IV Injection should be administered intravenously over a period of approximately 15 minutes at a rate of approximately 7 ml/min.

For Duodenal ulcer, gastric ulcer, and gastro-esophageal reflux disease associated with a history of erosive esophagitis: Pantex® IV Injection should be reconstituted with

10 ml of 0.9% Sodium Chloride solution, and further diluted with 100 ml of 5% Dextrose solution, 0.9% Sodium Chloride solution, or Lactated Ringer's solution, to a final concentration of approximately 0.4 mg/ml.

For Zollinger-Ellison syndrome (and other hypersecretory conditions): Pantex® IV Injection should be reconstituted with 10 ml of 0.9% Sodium Chloride solution. The contents of the two vials should be combined and further diluted with 80 ml of 5% Dextrose solution, 0.9% Sodium Chloride solution, or Lactated Ringer's solution, to a total volume of 100 ml with a final concentration of approximately 0.8 mg/ml.

Note: The reconstituted solution may be stored for up to 6 hours at room temperature prior to further dilution. The admixed solution may be stored at room temperature and must be used within 24 hours from the time of initial reconstitution. Both the reconstituted solution and the admixed solution do not need to be protected from light.

Use in pregnancy and lactation: No data is available on administration of Pantoprazole to pregnant women. However, this drug can be used during pregnancy only if clearly needed. There is no information about the safety of Pantoprazole during breast-feeding in humans. Pantoprazole should not be used during breast-feeding unless the benefit exceeds the potential risk.

Side effects: No potentially life threatening side-effects or serious adverse reactions has been reported. In some few cases headache, diarrhea, upper abdominal pain, constipation, flatulence, nausea, vomiting, dizziness, dry mouth, arthralgia, blurred vision, pruritis and skin rash have been reported.

Contraindications: Pantoprazole is contraindicated to those patients who have known hypersensitivity to any component of the formulation. Pantoprazole should not be co-administered with Atazanavir.

Precautions: Patients should be cautioned that Pantoprazole enteric coated pellets for capsule should not be spliced, chewed or crushed. Pantoprazole injection is for intravenous administration only and must not be given by any other route.

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 P450 system, no clinically significant interaction was observed 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.

Overdose: There are no known symptoms of overdosage in humans. Since Pantoprazole is highly protein bound, it is not removed by hemodialysis. In case of overdose, treatment should be symptomatic and supportive.

Pharmaceutical precautions: Store in a cool dry place. Protect from light

Presentation:

Pantex® 20: Each delayed release capsule contains pantoprazole 20 mg as Sodium Sesquihydrate 1NN.

Pantex® 40: Each delayed release capsute contains pantoprazole 40 mg as Sodium Sesquihydrate INN.

Pantex® 40 IV Injection: Each vial contains pantoprazole 40 mg as Sodium Sesquihydrate INN.

Package quantities:

Pantex® 20: Carton of 40 capsules in blister

Pantex® 40: Carton of 40 capsules in blister

Pantex® 40 IV Injection: Carton of one vial 40mg **Pantex®** Injection, 10 ml water for injection BP for intravenous injection & one 10ml syringe.

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