Pantobex®

Pantoprazole
Tablet/IV Injection

Description

Pantoprazole is chemically a novel substituted benzimidazole derivative, which suppresses the final step in gastric acid production by forming a covalent bond to two sites of H^+-K^+ATPase enzyme system at the secretory surface of the gastric parietal cell. This leads to inhibition of both basal and stimulated gastric effect that persists longer than 24 hours. Pantoprazole is quantitatively absorbed and its bioavailability does not change upon multiple dosing. Pantoprazole is extensively metabolized in the liver. Almost 80% of an oral dose is excreted as metabolites in urine; the remainder is found in feces.

Indications

Pantobex® is indicated where suppression of acid secretion is of therapeutic benefit. *Pantoprazole is registered in the following indications:*

- Peptic ulcer diseases (PUD)
- Gastro-esophageal reflux diseases
- Treatment of ulcer resistant to H_2 blocker
- Treatment of ulcer induced by NSAIDs
- GI bleeding from stress or acid peptic diseases
- Eradication of Helicobacter pylori
- Zollinger-Ellison syndrome
- Prophylaxis for acid aspiration syndrome during induction of anesthesia

Dosage and Administration

Pantobex® Tablet

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

Duodenal ulcers: Pantoprazole 40 mg tablet once daily for 2-4 weeks.

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

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

Ulcers induced by NSAIDs: Pantoprazole 40 mg tablet once daily.

Maintenance therapy: Maintenance therapy should involve the lowest effective dose of the drug. Pantoprazole both 20 mg & 40 mg doses are safe and effective in maintaining patients with healed reflux esophagitis and PUD in remission.

Pantobex® 40 IV Injection

Treatment of Gastroesophageal Reflux Disease associated with a history of erosive esophagitis: The recommended adult dose is 40 mg Pantoprazole given once daily by intravenous infusion for 7 to 10 days. *Pathological Hypersecretion Associated with Zollinger-Ellison Syndrome:* The recommended adult dosage is 80 mg q12h. The frequency of dosing can be adjusted to individual patient needs based on acid output measurements.

Contraindications

It is contraindicated in patients with known hypersensitivity to Pantoprazole.

Precautions

Patients should be cautious that Pantoprazole tablets should not be spilt, chewed or crushed.

Use in Pregnancy and Lactation

There are no adequate or well-controlled studies in pregnant women. Pantoprazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known whether Pantoprazole is excreted in human breast milk. Pantoprazole should be used during lactation only if the potential benefit justifies the potential risk.

Adverse Effects

No potentially life-threatening effects have been reported with Pantoprazole. Symptomatic adverse effects include headache and diarrhoea are two common reported adverse effects. Peripheral edema has been occasionally reported in female patients. Other side effects may include abdominal pain, dizziness, nausea, epigastric discomfort, flatulence, skin rash, pruritus etc.

Drug Interactions

There is no interaction with concomitantly administered antacids. No dosage adjustment is needed with combination use of the following drugs: Theophylline, Caffeine, Diazepam, Digoxin, Ethanol, Metoprolol, Nifedipine or Warfarin.

Pharmaceutical Precautions

Store in a cool, dry place and away from light. Keep out of the reach of children.

Commercial Pack

Pantobex® 20 tablet: Box containing 100 tablets in 10x10's Alu-Alu form packs. Each tablet contains Pantoprazole Sodium USP equivalent to Pantoprazole 20 mg.

Pantobex® 40 tablet: Box containing 100 tablets in 10 x 10's Alu-Alu form packs. Each tablet contains Pantoprazole Sodium USP equivalent to Pantoprazole 40 mg.

Pantobex® 40 IV Injection: Each commercial box containing one vial of sterile lyophilized powder of Pantoprazole Sodium sesquihydrate BP equivalent to Pantoprazole 40 mg, one ampoule of 0.9% Sodium Chloride Injection BP 10 ml for intravenous injection and one sterile disposable syringe (10 ml).

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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