

Panotem[®]

Pantoprazole

COMPOSITION:

Panotem[®] 20 Tablet: Each enteric coated tablet contains Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 20 mg.

Panotem[®] 40 Tablet: Each enteric coated tablet contains Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 40 mg.

PHARMACOLOGY:

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 the H⁺/K⁺ - ATPase enzyme system at the secretory surface of the gastric parietal cell. This leads to inhibition of both basal and stimulated gastric acid secretion irrespective of the stimulus. The binding to the H⁺/K⁺ - ATPase results in duration of antisecretory effect that persists longer than 24 hours. Pantoprazole is quantitatively absorbed and 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 and originates from biliary secretion.

INDICATION:

Panotem[®] Tablet is indicated where suppression of acid secretion is of therapeutic benefit. Panotem[®] Tablet is registered for the following indications: -

- Peptic ulcer diseases (PUD)
- Gastro esophageal reflux diseases (GERD)
- Treatment of ulcer resistant to H₂ receptor antagonists (H₂RAs)
- Treatment of ulcers induced by non-steroidal anti-inflammatory drugs (NSAIDs)
- Gastrointestinal (GI) 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 & ADMINISTRATION:

Panotem [®] Tablet	
Disease	Dosage 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.
Gastro esophageal reflux diseases (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.
Zollinger-Ellison Syndrome	40 mg 4 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.
Eradication of <i>Helicobacter pylori</i>	40 mg twice daily by triple therapy with antibiotics.
Ulcer resistant to H ₂ receptor antagonists	20 mg daily as a maintenance therapy, increased to 40 mg daily if symptoms return.

CONTRA-INDICATION:

Pantoprazole is contraindicated in patients with known hypersensitivity to any of the components of the formulation.

WARNING AND PRECAUTION:

Patients should be cautioned that Panotem[®] tablet should not be split, chewed or crushed. Long-term therapy of Pantoprazole may lead to malabsorption of cyanocobalamin (Vitamin B12) or may increase the risk of osteoporosis related disorders.

SIDE EFFECTS:

Potentially life-threatening effects: None has been reported with respect to Pantoprazole. Severe or irreversible adverse effects: No serious adverse reactions have been described to date. Symptomatic adverse effects: Headache (1.3%) and diarrhoea (1.5%) are the two commonest reported adverse events. It doesn't influence renal, cardiovascular, respiratory, endocrine, cognitive or motor functions and no consistent change have been found in any biochemical or haematological parameters. Peripheral edema has occasionally been reported in female patients. Other side effects may include abdominal pain, dizziness, nausea, epigastric discomfort, flatulence, skin rash, pruritus etc.

USE IN PREGNANCY & LACTATION:

Pregnant women: USFDA pregnancy category B. Studies using animals have not found any risk to fetus.

Lactating mother: There are no data on the excretion of Pantoprazole into the breast milk.

USE IN CHILDREN & ADOLESCENTS:

The safety and effectiveness of Pantoprazole for short-term treatment (up to eight weeks) of Erosive Esophagitis (EE) associated with GERD have been established in pediatric patients 1 year through 16 years of age.

Geriatric use: No problems with Pantoprazole have been reported in this patients group.

DRUG INTERACTION:

Pantoprazole is metabolized through the cytochrome P-450 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 concomitant use of the following drugs ; Theophylline, Antipyrine, Caffeine, Carbamazepine, Diazepam, Diclofenac, Digoxin, Ethanol, Glyburide, an oral contraceptive (Levonorgestrel/ Ethinyl Estradol), Metoprolol, Nifedipine, Phenyton or Warfarin. There was also no interaction with concomitantly administered antacids.

OVERDOSE:

There are no known symptoms of overdosage in humans.

STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Panotem[®] 20 Tablet: Each box contains 5 x 10's tablet in Alu-Alu blister pack.

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Manufactured by

Team Pharmaceuticals Ltd.

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