

Pamel

Pantoprazole

COMPOSITION:

Pamel 20 Tablet: Each enteric coated tablet contains Pantoprazole Sodium Sesquihydrate INN equivalent to Pantoprazole 20 mg.

Pamel 40 Tablet: Each enteric coated tablet contains Pantoprazole Sodium Sesquihydrate INN equivalent to Pantoprazole 40 mg.

PHARMACOLOGY:

Pamel (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. **Pamel** (Pantoprazole) is quantitatively absorbed and bioavailability does not change upon multiple dosing. **Pamel** (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:

Pamel (Pantoprazole) is indicated where suppression of acid secretion is of therapeutic benefit. **Pamel** (Pantoprazole) 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 anaesthesia

DOSAGE AND ADMINISTRATION:

- *Gastro esophageal reflux disease*, 20-40 mg daily for 4 weeks continued for further 4 weeks if not fully healed; may be continued at 20 mg daily (long-time management), increased to 40 mg daily if symptoms return.
- *Duodenal ulcer*, 40 mg daily for 2 weeks, continued for further 2 weeks if not fully healed.
- *Duodenal ulcer associated with Helicobacter pylori*, Pantoprazole 20 mg 3-4 times daily in combination with appropriate antibiotic. NSAID-induced peptic ulcer: 20 mg daily.
- *Zollinger-Ellison Syndrome*, the recommended oral dosage is one gastro-resistant pantoprazole tablet 20 mg twice daily.

SIDE EFFECT:

Pantoprazole is well tolerated in both short term and long term treatment. Headache and diarrhoea are the most common side effects and rarely included abdominal pain, flatulence, rash, insomnia and hyperglycemia.

CONTRAINDICATION:

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

PRECAUTION:

Patients should be cautioned that Pantoprazole tablet should not be split, crushed or chewed. The tablet should be swallowed whole, with or without food in the stomach. Concomitant administration of antacid does not affect the absorption of Pantoprazole.

Pamel

Pantoprazole

USE IN PREGNANCY AND LACTATION:

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

Neonates & Children: No data are available on administration of Pantoprazole.

DRUG INTERACTION:

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 Estrada), metoprolol, nifedipine, phenytoin, warfarin, 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 (e.g. ketoconazole, ampicillin ester and iron salts).

OVERDOSAGE:

There are no known symptoms of overdosage in humans. Since Pantoprazole is highly protein bound, it is not readily dialyzable. Apart from symptomatic and supportive management, no specific therapy is recommended.

PHARMACEUTICALS PRECAUTION:

It should be stored in a cool and dry place, protected from light and moisture.

HOW SUPPLIED:

Pamel 20 Tablet: Each box Box contains 5 x10 tablets in Alu-Alu blister pack.

Pamel 40 Tablet: Each box Box contains 5 x10 tablets in Alu-Alu blister pack.

Manufactured By:



MEDICON Pharmaceuticals Ltd
Mirpur, Dhaka, Bangladesh