

AciPan-40

(Pantoprazole Sodium Tablets)

Each enteric coated tablet contains: Pantoprazole Sodium IP

Eq. to Anhydrous Pantoprazole.....40 mg
Excipients.....q.s.

Clinical Pharmacology:

Pantoprazole: Pantoprazole inhibits the hydrogen/potassium ATPase enzyme (proton pump) in the gastric parietal cells, leading to a significant reduction in gastric acid secretion. This action is dose-dependent and provides both short-term and long-term control of gastric acid.

Indications:

- Treatment of GERD and other condition associated with excessive gastric acid secretion
- Maintenance therapy for patients with healed erosive esophagitis
- Prevention of gastric ulcers in patients taking NSAIDs

Contraindications:

- **Allergy to Pantoprazole or Proton Pump Inhibitors:** Hypersensitivity to pantoprazole or any components of the formulation is a contraindication.
- **Severe Hepatic Impairment:** Caution is advised in patients with severe liver disease, as metabolism and clearance may be affected.
- **Use in Combination with Certain Medications:** Concomitant use with drugs that are highly dependent on CYP2C19 for metabolism (e.g., clopidogrel) should be approached with caution, as pantoprazole may reduce their effectiveness.

Precautions:

- **Allergic Reactions:** Watch for signs of hypersensitivity.
- **Hepatic Impairment:** Use cautiously in liver disease; may require dosage adjustments.

- **Long-Term Use:** Risks include vitamin B12 deficiency, bone fractures, and kidney disease.
- **Gastrointestinal Conditions:** Caution in patients with a history of gastric cancer, as it may mask symptoms.

Cautions:

- **Pregnancy and Breastfeeding:** Discuss risks and benefits with a healthcare provider.
- **Renal Impairment:** Increased risk of adverse effects in kidney disease.
- **Infections:** May increase risk of gastrointestinal infections like *C. difficile*.
- **Comprehensive Medication Review:** Inform your provider about all medications to check for interactions.

Drug Interactions:

- **CYP2C19 Interactions: Clopidogrel:** Pantoprazole may reduce the effectiveness of clopidogrel, a medication used to prevent blood clots, by inhibiting CYP2C19,
- **CYP3A4 Substrates: Drugs Metabolized by CYP3A4:** While pantoprazole is primarily a CYP2C19 inhibitor, it may also affect the metabolism of drugs that are substrates of CYP3A4, leading to altered levels.
- **Absorption of Acid-Dependent Medications: Certain Antifungals (e.g., ketoconazole, itraconazole):** The absorption of these medications may be reduced in a less acidic environment created by pantoprazole.
- **Methotrexate:** High doses of methotrexate may interact with PPIs, potentially leading to increased methotrexate levels and toxicity.
- **Warfarin:** Monitor INR closely, as pantoprazole may affect the metabolism of warfarin, leading to increased anticoagulation effects.
- **Digoxin:** Pantoprazole may increase digoxin levels, necessitating monitoring for digoxin toxicity.

Adverse Effects:

- **Allergic Reactions:** Anaphylaxis or severe hypersensitivity reactions.
- **Gastrointestinal:** Clostridium difficile infection in the colon.
- **Renal Issues:** Acute interstitial nephritis or other kidney-related problems.
- **Bone Fractures:** Increased risk of hip, wrist, and spine fractures with long-term use.
- **Vitamin Deficiencies:** Vitamin B12 deficiency due to long-term suppression of gastric acid.
- **Hypomagnesemia:** Low magnesium levels, which can lead to muscle spasms, irregular heartbeat, or seizures.

Overdosage :

Symptoms:

Gastrointestinal: Nausea, vomiting, diarrhea, abdominal pain.

Neurological: Dizziness, headache, and confusion may occur.

Other Effects: Fatigue and general malaise.

Management:

Immediate Care: Seek medical attention if overdose is suspected.

Supportive Treatment: There is no specific antidote; management focuses on supportive care and symptomatic relief.

Monitoring: Vital signs and electrolyte levels may need to be monitored, especially magnesium.

Route of Administration: Oral. Swallow it as a whole. Do not chew, crush or break it.

SCHEDULE H PRESCRIPTION DRUG CAUTION: Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Dosage: As directed by the Physician.

Storage: Store in a cool, dry place protected from light.

Presentation: It is available as 10x10 Tablets.



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