

# Pantoprazole

## Acernix

40 mg Tablet

PROTON PUMP INHIBITOR

### FORMULATION:

Each enteric coated tablet contains:  
Pantoprazole Sodium Sesquihydrate B.P.  
equivalent to Pantoprazole.....40 mg

### PHARMACOKINETICS:

It is rapidly absorbed after oral administration. The drug is subject to low first-pass hepatic extraction, displaying an estimated absolute oral bioavailability of 77%. Concomitant food intake does not affect bioavailability. Elimination is predominantly renal, with 80% of an oral or intravenous dose being excreted as urinary metabolites, the remainder is excreted in the faeces and originates primarily from biliary secretion.

### INDICATION:

*Treatment of Gastroesophageal Reflux Disease Associated with a History of Erosive Esophagitis.*

Pantoprazole is indicated for short term treatment (7 to 10 days) of patients with gastroesophageal reflux disease (GERD) and a history of erosive esophagitis.

*Pathological Hypersecretion Associated with Zollinger-Ellison Syndrome*

Pantoprazole is indicated for the treatment of pathological hypersecretory conditions associated with Zollinger-Ellison Syndrome or other neoplastic conditions.

### CONTRAINDICATION:

Contraindicated in patients with known hypersensitivity to any component of the formulation.

### DRUG INTERACTION:

Phenazone (antipyrene), diazepam, digoxin, theophylline, carbamazepine, diclofenac, phenprocoumon, phenytoin, warfarin, nifedipine, caffeine, metoprolol or ethanol: No clinically relevant interaction at therapeutic doses. Oral contraceptives: Does not appear to compromise hormonal contraceptive efficacy as no interaction with low dose combined oral contraceptive has been seen.

### ADVERSE EFFECTS:

The most common side effects are headache, diarrhea, dizziness, pruritus, skin rash, flatulence, abdominal pain, rash, eructation, insomnia, and hyperglycemia.

### PRECAUTION:

Symptomatic response does not preclude gastric malignancy; not indicated for maintenance therapy; safety and efficacy for use beyond 16 weeks have not been established; safety and efficacy in pediatric patients have not been established.

### DOSAGE AND ADMINISTRATION:

**Treatment of Erosive Esophagitis:** The recommended adult oral dose is 40 mg given once daily for up to 8 weeks. For those patients who have not healed after 8 weeks of treatment, an additional 8-week course of pantoprazole may be considered.

**Treatment of Peptic ulcer disease:** 40 mg once daily. Treatment is usually given for 2 to 4 weeks for duodenal ulceration, or 4 to 8 weeks for benign gastric ulceration. For the eradication of *Helicobacter pylori* pantoprazole may be combined with two antibacterials in a 1-week triple therapy regimen. Effective regimens include pantoprazole 40 mg twice daily combined with clarithromycin 500 mg twice daily and either amoxicillin 1 g twice daily or metronidazole 400 mg twice daily.

**Children:** Not recommended for use in children under 12 years of age. Or as prescribed by the physician.

### AVAILABILITY:

Pantoprazole 40 mg Tablet, Packed in Alu-Alu blister pack of 10 tablets; Box of 50's


### CAUTION:

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

### STORE AT TEMPERATURES NOT EXCEEDING 30°C.

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