

# Trupan®

## Pantoprazole

### COMPOSITION

**Trupan® 20 Tablet:** Each delayed release tablet contains Pantoprazole sodium sesquihydrate BP equivalent to Pantoprazole 20 mg. **Trupan® 40 Tablet:** Each delayed release tablet contains Pantoprazole sodium sesquihydrate BP equivalent to Pantoprazole 40 mg. **Trupan® 40 IV Injection:** Each vial contains Pantoprazole 40 mg (as lyophilized powder of Pantoprazole sodium sesquihydrate BP) and each ampoule contains 10 ml of 0.9% Sodium Chloride Injection BP.

### PHARMACOLOGY

Pantoprazole, a substituted benzimidazole, is an inhibitor of gastric acid secretion. Pantoprazole inhibits secretion of gastric acid by blocking the hydrogen-potassium-adenosine triphosphatase enzyme system, the so called 'Proton Pump' of the gastric parietal cell. Absorption of Pantoprazole begins only after the tablet leaves the stomach. Peak serum concentration ( $C_{max}$ ) and area under the serum concentration time curve (AUC) increase in a manner proportional to oral dose from 10 mg to 80 mg. Pantoprazole does not accumulate and its pharmacokinetics are unaltered with multiple daily dosing. Following oral administration, the serum concentration of Pantoprazole declines biexponentially with a terminal elimination half-life of approximately one hour. The absorption of Pantoprazole is rapid, with a  $C_{max}$  of 2.5 mcg/ml, which occurs approximately 2.5 hours after single or multiple oral 40-mg doses. Pantoprazole is well absorbed. It undergoes little first-pass metabolism resulting in an absolute bioavailability of approximately 77%. Administration of Pantoprazole with food may delay its absorption up to 2 hours or longer. However, the  $C_{max}$  and the extent of Pantoprazole absorption (AUC) are not altered. Thus, Pantoprazole may be taken without regard to timing of meals. The serum protein binding of Pantoprazole is about 98%, primarily to albumin. Pantoprazole is extensively metabolized in the liver through the cytochrome P450 (CYP) system. After a single oral dose of  $^{14}C$ -labeled Pantoprazole to healthy, normal metabolizer volunteers, approximately 71% of the dose was excreted in the urine with 18% excreted in the feces through biliary excretion. There was no renal excretion of unchanged Pantoprazole.

### INDICATION

Benign gastric ulcer, duodenal ulcer, gastroesophageal reflux disease (GERD), NSAID-induced peptic ulcer, acid hypersecretory conditions including Zollinger-Ellison Syndrome, eradication of *Helicobacter pylori* (in combination with Antibiotics), ulcer resistant to  $H_2$  receptor antagonists.

### DOSAGE & ADMINISTRATION

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.
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

**Children:** Safety and effectiveness have not been established

Injection	
Duodenal ulcer and gastric ulcer	40 mg once daily for 7-10 days
Gastroesophageal reflux disease associated with a history of erosive esophagitis	40 mg once daily for 7-10 days
Prevention of rebleeding in peptic ulcer	IV 80 mg, followed by 8 mg/hour infusion for 72 hours
Prophylaxis of acid aspiration	80 mg IV every 12 h for 24 h, followed by 40mg every 12 h
Long-term management of Zollinger-Ellison Syndrome and other pathological hypersecretory conditions	80 mg IV every 12 hours, may increase to 80 mg every 8 hours if needed, may titrate to higher doses depending on acid output.

Intravenous Pantoprazole should be replaced with oral therapy as soon as possible.

### DIRECTION FOR USE OF IV INJECTION

Pantoprazole lyophilized powder and 0.9% Sodium Chloride Injection is for intravenous administration only and must not be given by any other route. Pantoprazole IV injection should be given as a slow intravenous injection. The solution for IV injection is obtained by adding 10 ml 0.9% Sodium Chloride Injection to the vial containing powder. After reconstitution the injection should be given slowly over a period of at least 2 to 5 minutes. Use only freshly prepared solution. The reconstituted solution may be stored at room temperature (up to 30°C) for a maximum 4 hours.

### DIRECTION FOR USE OF IV INFUSION

Pantoprazole IV infusion should be given as an intravenous infusion over a period of approximately 15 minutes. Pantoprazole IV infusion should be reconstituted with 10 ml of 0.9% Sodium Chloride Injection and further diluted (admixed) with 0.9% Sodium Chloride Injection or 5% Dextrose or Lactated Ringer's Injection to a final volume of 100 ml. The reconstituted solution may be stored at room temperature (up to 30°C) for a maximum 4 hours prior to further dilution. The admixed solution may be stored at room temperature (up to 30°C) and must be used within 24 hours from the time of initial reconstitution.

### 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.

### USE IN PREGNANCY AND LACTATION

Teratology studies have been performed in animals and have revealed no evidence of impaired fertility or harm to the fetus due to Pantoprazole. There are no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Pantoprazole excretion in human milk has been detected in a study of a single nursing mother after a single 40 mg oral dose. The clinical relevance of this finding is not known. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

### 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.

### 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, desmethyl-diazepam), diclofenac, naproxen, piroxicam, digoxin, ethanol, glyburide, oral contraceptive (levonorgestrel/ethinyl estradiol), 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.

### STORAGE CONDITION

Store in a cool (below 25°C) and dry place, protected from light and moisture.

### HOW SUPPLIED

**Trupan® 20 Tablet:** Box containing 60's tablets in Alu-Alu blister pack. **Trupan® 40 Tablet:** Box containing 60's tablets in Alu-Alu blister pack. **Trupan® 40 IV Injection:** Each box contains one vial of lyophilized Pantoprazole 40 mg, one ampoule of 10 ml 0.9% Sodium Chloride Injection and one sterile disposable syringe (10 ml).

Manufactured by:



**SQUARE**  
PHARMACEUTICALS LTD.  
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