

# ZOPAN Tablet

Pantoprazole INN

## Presentation :

ZOPAN-20 Tablet : Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate INN equivalent to Pantoprazole 20 mg.

ZOPAN-40 Tablet : Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate INN equivalent to Pantoprazole 40 mg.

## Description :

Zopan (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 anti-secretory effect that persists longer than 24 hours. Zopan (Pantoprazole) is extensively metabolized in the liver. Almost 80% of an oral dose is excreted as metabolites in urine; the remainder is found in faeces and originates from biliary secretion.

## Indications and Usage :

Zopan (Pantoprazole) is indicated where suppression of acid secretion of therapeutic benefit.

Zopan (Pantoprazole) is registered for the following indications :

1. Peptic ulcer diseases (PUD)
2. Gastro esophageal reflux diseases (GERD)
3. Treatment of ulcer resistant to  $H_2$  receptor antagonists ( $H_2$  R As)
4. Treatment of ulcer induced by non-steroidal anti-inflammatory drugs (NSAIDs)
5. Gastrointestinal (GI) bleeding from stress or acid peptic diseases
6. Eradication of *Helicobacter pylori* (in combination with antibiotics)
7. Zollinger-Ellison syndrome
8. Prophylaxis for acid aspiration syndrome during induction of anaesthesia

## Dosage and Administration :

The recommended once daily dosage of pantoprazole should be taken in the morning. ZOPAN-20 and ZOPAN-40 should be swallowed whole with a little water either before or during breakfast.

### Duodenal ulcer :

The recommended oral dosage is 40 mg pantoprazole once daily in the morning for 2 to 4 weeks. If the duodenal ulcer has been demonstrated to be associated with *Helicobacter pylori* infection, ZOPAN-40 used in combination with appropriate antibiotics may be useful.

### Gastric ulcer :

The recommended oral dosage is 40 mg pantoprazole once daily in the morning for 4 to 8 weeks.

In the case of a suspected gastric ulcer, malignancy of the ulcer should be excluded, as treatment could conceal the symptoms and may delay diagnosis.

### Reflux oesophagitis :

The recommended oral dosage is 40 mg pantoprazole once daily in the morning for 4 to 8 weeks.

### Mild Gastro-esophageal reflux disease (GERD) :

The recommended oral dosage is 20 mg pantoprazole per day. A 4-week period is usually required for healing of mild GERD. If this is not sufficient, healing will usually be achieved within a further 4 weeks.

### Long-term management and prevention of relapse in GERD :

For long-term management a maintenance dose of one ZOPAN- 20 tablet per day is recommended, increasing to 40 mg pantoprazole per day if a relapse occurs. After healing of the relapse, the dosage can be reduced to 20 mg pantoprazole.

### Elderly patients :

No dosage adjustment is necessary in the elderly.

### Impaired renal and liver function :

No dosage adjustment is required in the presence of impaired renal and liver function. A daily dose of 20 mg pantoprazole should not be exceeded in patients with mild to moderate severe hepatic cirrhosis.

### Contraindication :

Zopan delayed release tablets are contraindicated in patients with known hypersensitivity to any of the formulation.

### Precautions :

Patients should be cautioned that Zopan delayed release tablets should not be split, chewed or crushed.

### Side effects :

Potentially life-threatening effects : None has been reported with respect to pantoprazole.

Symptomatic adverse effects : Headache (1.3%) and diarrhoea (1.5%) are to 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.

### Drug Interactions :

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 with concomitant use of the following drugs: theophylline, antipyrine, caffeine, carbamazepine, diazepam, diclofenac, digoxin, ethanol, glyburide, an oral contraceptive (Levonorgestrel/ethinyl estradiol), metoprolol, nifedipine, phenytoin or warfarin. There was also no interaction with concomitantly administered antacids.

### Commercial Pack :

Zopan - 20 Tablet : Each box contains 5 x 10 tablets in blister pack.

Zopan - 40 Tablet : Each box contains 5 x 10 tablets in blister pack.

Manufactured by :

 **KEMIKO PHARMACEUTICALS LTD.**

BANGLADESH