xxxxxxxx-5343

PANTOPRAZOLE

PANTOR-20

20 mg Enteric-Coated Tablet
Proton Pump Inhibitor

FORMULATION
Each enteric-coated tablet contains:
Pantoprazole (as sodium sesquihydrate) ..... 20 mg

PRODUCT DESCRIPTION
Pantoprazole (Pantor-20) 20 mg is a yellow colored, oval shape, biconvex, enteric-coated tablet, plain on both sides.

CLINICAL PHARMACOLOGY
Mechanism of Action
Pantoprazole is a proton pump inhibitor, it inhibits specifically and dose proportionally H+, K+-ATPase, the enzyme which is responsible for gastric secretion in the parietal cells of the stomach.
Pantoprazole is a substituted benzimidazole which accumulates in the acidic compartment of the parietal cells after absorption. In the parietal cell, it is protonated and chemically re-arranged to the active inhibitor, a cyclic sulphenamide, which binds to the H+, K+-ATPase, thus inhibiting the proton pump and causing suppression of stimulated and basal gastric acid secretion after single and multiple intravenous and oral pantoprazole dosing. Because pantoprazole acts distal to the receptor level, it can influence gastric acid secretion irrespective of the nature of the stimulus.
Pantoprazole exerts its full effect in a strongly acidic environment (pH<3) and remains mostly inactive at higher pH values, which explains its selectivity for the acid secreting parietal cells of the stomach. Therefore, the complete pharmacologic and therapeutic effect of pantoprazole can only be achieved in the acid-secreting parietal cells. By means of a feedback mechanism this effect is diminished at the same rate as acid secretion is inhibited.
Effect on Gastric Acid Secretion
The mean inhibition of pentagastrin stimulated acid output after 40mg/day is 85% after seven days, 21/2 to 31/2 hours after dosing. After stopping the intake of pantoprazole, there is no evidence of rebound hypersecretion and 7 days after taking the last dose, the acid output is normal.
Pantoprazole maintains the physiological pH-rhythm. The values, however, are shifted to higher levels. During the night, periods with pH values approximating placebo have been found. Although, pantoprazole has a half-life of approximately 1 hour, the antisecretory effect increases, demonstrating that the duration of action markedly exceeds the serum elimination half-life.

PHARMACOKINETICS
Absorption and Distribution
Pantoprazole is unstable in acid and is administered orally in the form of an enteric-coated tablet. Absorption takes place in the small intestine. On average, the maximum serum/plasma concentrations are approximately 2 to 3 mcg/mL about 21/2 hours after administration of 40 mg pantoprazole daily, as a single or multiple dose in healthy volunteers. The absolute systemic bioavailability of pantoprazole from single and multiple oral doses of pantoprazole is approximately 77%.
The plasma kinetics for pantoprazole after both oral and intravenous administration are linear over the dose range 10-80 mg.
Metabolism
Pantoprazole is almost exclusively metabolized in the liver. The main metabolite is desmethylpantoprazole which is conjugated with sulphate.
Elimination
Renal elimination represents the most important route of excretion (approximately 80%) for the metabolites of pantoprazole. The balance is excreted in the feces. The half-life of the main metabolite is approximately 1½ hours which is slightly longer than that of pantoprazole.
Pharmacokinetic Profile in Patients
In subpopulations of subject suffering from mild to moderately severe liver cirrhosis, the half-life increases from 1 hour to between 7 to 9 hours. The AUC values are increased by a factor of 6 to 8, while the maximum serum concentration increases by a factor of only ½ in comparison with healthy subjects.
In patients with renal impairment the half-life of the main metabolite is moderately increased but there is no accumulation at therapeutic dose. The half-life of pantoprazole in patients with renal impairment is comparable to the half-life of pantoprazole in healthy subjects. Pantoprazole is poorly dialyzable. A slight increase in AUC and C_{max} occurs in elderly volunteers compared with younger people.

INDICATIONS
It is used in conditions where inhibition of gastric acid secretion maybe beneficial including aspiration syndromes, dyspepsia, gastro-oesophageal reflux disease, peptic ulcer disease and the Zollinger-Ellison Syndrome.

CONTRAINDICATIONS
Hypersensitivity to pantoprazole. Safety in pregnancy and during lactation has not been established. Safety and efficacy in children have not been established. Severely impaired liver function.

DOSAGE AND ADMINISTRATION
The recommended once daily dosage of pantoprazole should be taken in the morning. Pantoprazole tablets should not be chewed or crushed, and should be swallowed whole with water 1 hour before breakfast

Gastro-Esophageal Reflux Disease: The usual dose is 20 mg to 40 mg once daily for 4 weeks, increased to 8 weeks if necessary. For maintenance therapy, treatment can be continued with 20 to 40 mg daily.
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.
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.
NSAID-associated ulceration - 20 mg daily.
Zollinger-Ellison syndrome: Initial dose of 80 mg , adjusted as required. Daily doses greater than 80 mg should be given in 2 divided doses.
Administration in Hepatic Impairment: Dosage may need to be reduced in severe hepatic impairment, or doses given only on alternate days. A maximum dose of 20 mg daily, or 40 mg on alternate days.
Administration in Renal Impairment: Maximum dose of 40 mg should be observed.

ADVERSE EFFECTS
Headaches and gastro-intestinal complaints such as upper abdominal pain, diarrhea, constipation or flatulence have been reported. With continued treatment complaints usually diminish. There have been reports of allergic reactions such as skin rash, pruritus and in isolated cases also urticaria, angioedema or anaphylactic shock. There have been less frequent reports of nausea, dizziness or disturbances in vision (blurred vision). Peripheral edema, depression, fever or myalgia have been reported in individual cases.

"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph or to TORRENT: www.torrentpharma.com".
Patient to seek medical attention immediately at the first sign of any adverse drug reaction shall appear.

SPECIAL PRECAUTIONS
Pantoprazole is not indicated for mild gastro-intestinal complaints such as nervous dyspepsia. Prior to treatment, the possibility of a malignant gastric ulcer or a malignant disease of the esophagus should be excluded, as the treatment with pantoprazole may alleviate the symptoms of malignant ulcers and can delay diagnosis. Diagnosis of reflux esophagitis should be confirmed by endoscopy.

DRUG INTERACTIONS
May prolong the elimination of diazepam, phenytoin and warfarin. Pantoprazole can reduce the absorption of drugs such as ketoconazole, and possibly itraconazole, whose absorption is dependent on an acid gastric pH.

STORAGE CONDITION
Store at temperatures not exceeding 30°C.

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

AVAILABILITY
Pantoprazole (Pantor-20) 20 mg Enteric Coated Tablet- Alu-Alu Blister Pack of 10's (Box of 30's) - DRP-2744

DATE OF FIRST AUTHORIZATION
March 24, 2009

DATE OF REVISION
July 2016

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, India.

Imported and Distributed by :
TORRENT PHARMA PHILIPPINES INC.
Units 3 & 4, 34th Floor, Zuellig Building
Makati Avenue Corner Paseo de Roxas
Makati City, PHILIPPINES

PRODUCT NAME :	Pantor 20	**COUNTRY :** Philippines	**LOCATION :** Indrad		**Supersedes A/W No.:**		
ITEM / PACK :	Insert	**NO. OF COLORS:** 1	**REMARK :**				
DESIGN STYLE :	Front/Back	**PANTONE SHADE NOS.:**	**SUBSTRATE :**				
CODE :	xxxxxxx-5343	Black	**Activities**	**Department**	**Name**	**Signature**	**Date**
DIMENSIONS (MM) :	150 x 180		Prepared By	**Pkg.Dev**			
ART WORK SIZE :	S/S		Reviewed By	**Pkg.Dev**			
DATE :	21-07-2016		Approved By	**Quality**			