PANSPED

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Abbreviated Prescribing information for PANSPED Tablet (Pantoprazole sodium 40mg delayed release Tablet) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Pantoprazole is a proton pump inhibitor (PPI) that suppresses the final step in gastric acid production.

INDICATION: For treatment of Gastric ulcer, duodenal ulcer, Zollinger-Ellison Syndrome and Gastro esophageal Reflux Disease (GERD)

DOSAGE AND ADMINISTRATION: Pantoprazole 40 mg delayed release tablets should not be chewed or crushed, and should be swallowed whole with liquid before a meal.

CONTRAINDICATION: In patients with known hypersensitivity to any component of the formulation or any substituted benzimidazole. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, acute interstitial nephritis, and urticaria.

WARNINGS & PRECAUTIONS:

Hepatic Impairment In patients with severe liver impairment, the liver enzymes should be monitored regularly during treatment with pantoprazole, particularly on long-term use. *Gastric malignancy* Symptomatic response to pantoprazole may mask the symptoms of gastric malignancy and may delay diagnosis.In the presence of any alarm symptom. Co-administration of pantoprazole is not recommended with HIV protease inhibitors for which absorption is dependent on acidic intragastric pH such as atazanavir, due to significant reduction in their bioavailability. Influence on vitamin B12 absorption. In patients with Zollinger-Ellison syndrome and other pathological hypersecretory conditions requiring long-term treatment, pantoprazole, as all acid-blocking medicines, may reduce the absorption of vitamin B12 (cyanocobalamin) due to hypo- or achlorhydria. Gastrointestinal infections caused by bacteria Treatment with Pantoprazole may lead to a slightly increased risk of gastrointestinal infections caused by bacteria such as Salmonella and Campylobacter and C. difficile. Proton pump inhibitors are associated with very infrequent cases of SCLE (*Subacute cutaneous lupus erythematosus)*. SCLE after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors.

DRUG INTERACTIONS: The absorption of atazanavir is pH-dependent. Therefore, pantoprazole must not be co- administered with atazanavir. in settings where high- dose methotrexate is used, for example cancer and psoriasis, a temporary withdrawal of pantoprazole may need to be considered. In patients treated with coumarin anticoagulants (e.g. phenprocoumon or warfarin), monitoring of prothrombin time/INR is recommended after initiation, termination or during irregular use of pantoprazole.

ADVERSE REACTIONS: Uncommon: sleep disorders, Headache; Dizziness, Diarrhoea; Nausea / vomiting; Abdominal distension and bloating; Constipation; Dry mouth; Abdominal pain and discomfort, Liver enzymes increased (transaminases, γ-GT), Rash / exanthema /eruption; Pruritus,Asthenia, fatigue and malaise. **Rare:** Agranulocytosis, Hypersensitivity (incl. anaphylactic reactions and anaphylactic shock), Hyperlipidaemias and lipid increases (triglycerides, cholesterol); Weight changes, Depression (and all aggravations), Taste disorders, Disturbances in vision / blurred vision, Bilirubin increased, Urticaria; Angioedema, Arthralgia; Myalgia, Gynaecomastia, Body temperature increased; Oedema peripheral. **Very rare:** Thrombocytopeni a; Leukopenia, Pancytopenia, Disorientation (and all aggravations). **Not known:** Hyponatraemia,, Hypomagnesaemia

Hallucination; Confusion (especially in pre- disposed patients, as well as the aggravation of these symptoms in case of pre-existence), Hepatocellular injury; Jaundice; Hepatocellular failure, Stevens-Johnson syndrome; Lyell syndrome; Erythemamultiforme; Photosensitivity Subacute cutaneous lupus erythematosus, Interstitial nephritis; Acute Kidney Injury

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

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(Additional information is available on request)