

PANSPED 40

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only
Abbreviated Prescribing information for PANSPED 40 [Pantoprazole sodium 40mg Delayed release
Tablet]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Pantoprazole is a substituted benzimidazole which inhibits the secretion of hydrochloric acid in the stomach by specific blockade of the proton pumps of the parietal cells. Pantoprazole is converted to its active form, a cyclic sulphenamide, in the acidic environment in the parietal cells where it inhibits the H⁺, K⁺-ATPase enzyme, i. e. the final stage in the production of hydrochloric acid in the stomach.

INDICATIONS: 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: Hypersensitivity to the active substance, or to any of the excipients. Co-administration with atazanavir.

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), Hyperlipidemia and lipid increases (triglycerides, cholesterol); Weight changes, Depression (and all aggravations), Taste disorders, Disturbances in vision / blurred vision, Bilirubin increased, Urticaria; Angioedema, Arthralgia; Myalgia, Gynecomastia, Body temperature increased; Oedema peripheral. *Very rare:* Thrombocytopenia; 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; Erythema multiforme;
Photosensitivity Subacute cutaneous lupus erythematosus, Interstitial nephritis; Acute Kidney Injury

MARKETED BY:



Torrent Pharmaceuticals Limited.

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(Additional information is available on request)