PANSPED DSR

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

Abbreviated Prescribing information for PANSPED DSR [Pantoprazole Gastro-Resistant and Domperidone Prolonged –Release Capsules I.P.]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:
MECHANISM OF ACTION: *Pantoprazole:* Pantoprazole is a proton pump inhibitor (PPI) class of antisecretory agent. Pantoprazole is a lipophilic weak base that crosses the parietal cell membrane and enters the acidic parietal cell canaliculus where it becomes protonated, producing the active metabolite sulfenamide. Sulfenamide forms an irreversible covalent bond with two sites of the H+/K+-ATPase enzyme located on the gastric parietal cell. Thus, pantoprazole suppresses the final step in gastric acid (hydrochloric acid – HCl) production by covalently binding to the H+/K+-ATPase enzyme (also called as proton pump) system at the secretory surface of the gastric parietal cell. *Domperidone:* Domperidone is a dopamine receptor (D2) antagonist. Domperidone act predominantly on peripheral dopamine receptors and produces anti-emetic and gastrokinetic effects. Anti-emetic effect of domperidone is due to a combination of peripheral (gastrokinetic) effects and antagonism of dopamine receptors (D2) in the chemoreceptor trigger zone (CTZ), which lies outside the BBB in the area postrema.

INDICATIONS: For gastric ulcer, duodenal ulcer, Zollinger-Ellison-syndrome and Gastro-esophageal reflux diseases.

DOSAGE AND ADMINISTRATION: Recommended dose is 1 capsule to be administered once daily for 4 to 8 weeks. Pansped DSR capsules may be administered with or without food. The capsules should be swallowed whole with water and not to be opened, chewed or crushed. Or, as prescribed by the physician.

CONTRAINDICATION: •Patients with known hypersensitivity to pantoprazole or to any substituted benzimidazole derivative or to domperidone or to any component of the formulation, •In patients receiving rilpivirine-containing products, •Prolactin-releasing pituitary tumor (prolactinoma), •In patients with gastrointestinal hemorrhage, mechanical obstruction, or perforation (i.e., when stimulation of the gastric motility could be harmful), •In patients with moderate or severe hepatic impairment, •In patients who have known existing prolongation of cardiac conduction intervals, particularly QTc, •Patients with significant electrolyte disturbances (hypokalemia, hyperkalemia, hypomagnesemia) or underlying cardiac disease such as congestive heart failure (CHF), •Co-administration with QT-prolonging drugs. •Co-administration with potent CYP3A4 inhibitors.

WARNINGS & PRECAUTIONS: *Pantoprazole:* In adults, symptomatic response to therapy with pantoprazole does not preclude the presence of gastric malignancy. Acute interstitial nephritis may occur at any point during pantoprazole therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue pantoprazole if acute interstitial nephritis develops. Pantoprazole therapy may be associated with an increased risk of Clostridium Difficile-Associated Diarrhea (CDAD), especially in hospitalized patients, Proton pump inhibitors (PPIs), especially if used in high doses and over long durations (> 1 year), may modestly increase the risk of hip, wrist and spine fracture. Generally, daily treatment with any acid-suppressing medication over a long period of time (e.g., longer than 3 years) may lead to malabsorption of vitamin B12 caused by hypo- or achlorhydria. *Domperidone:* Domperidone has been associated with prolongation of the QT interval on the electrocardiogram. Epidemiological studies showed that domperidone was associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death.

DRUG INTERACTIONS: *Pantoprazole:* The effect of PPIs on antiretroviral drugs is variable. The clinical importance and the mechanisms behind these interactions are not always known. There have been post-marketing reports of increased international normalized ratio (INR) and prothrombin time in patients receiving PPIs, including pantoprazole, and warfarin concomitantly. A temporary withdrawal of pantoprazole therapy may be considered in some patients receiving high dose of methotrexate. Pantoprazole may reduce absorption of other drugs where gastric pH is an important determinant of their bioavailability. Use pantoprazole with caution in transplant patients receiving MMF. There have been reports of false positive urine screening tests for tetrahydrocannabinol (THC) in patients receiving PPIs, including pantoprazole. Pantoprazole treatment should be stopped for at least 5 days before CgA measurements. *Domperidone:* The concomitant use of drugs that significantly inhibit CYP3A4 may result in increased plasma levels of domperidone. There is increased risk of occurrence of QT-interval prolongation, due to

pharmacodynamic and/or pharmacokinetic interactions.

ADVERSE REACTIONS: *Pantoprazole:* Headache, diarrhea, nausea, abdominal pain, vomiting, flatulence, dizziness, arthralgia, allergic reaction, hepatitis, leukopenia, generalized edema, myalgia, depression, urticaria, rash, blurred vision, fatigue, malaise, pancytopenia, agranulocytosis, hyponatremia, rhabdomyolysis, bone fracture, ageusia, dysgeusia, interstitial nephritis, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN). *Domperidone:* hyperprolactinemia, galactorrhoea, gynecomastia, amenorrhea, convulsion, agitation, somnolence, asthenia, extrapyramidal disorder, convulsions, oculogyric crisis, ventricular arrhythmias, QTc prolongation, Torsade de Pointes, breast pain, breast tenderness, urinary retention, and abnormal liver function test.

MARKETED BY:

Torrent Pharmaceuticals Limited.

IN/PANSPED DSR 40/30 mg/FEB 2025/01/ABPI

(Additional information is available on request)