PANSPED I.V.

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

Abbreviated Prescribing information for PANSPED I.V. [Pantoprazole for injection I.P]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Pantoprazole is a PPI that suppresses the final step in gastric acid production by covalently binding to the (H, K)-ATPase enzyme system at the secretory surface of the gastric parietal cell. This effect leads to inhibition of both basal and stimulated gastric acid secretion irrespective of the stimulus. The binding to the (H, K)-ATPase results in a duration of antisecretory effect that persists longer than 24 hours for all doses tested (20 mg to 120 mg).

INDICATIONS: PANSPED I.V. is indicated for the treatment of duodenal ulcer, gastric ulcer, moderate and severe reflux oesophagitis.

DOSAGE AND ADMINISTRATION: The recommended adult dosage of PANSPED I.V. is 40 mg once daily by intravenous injection (over at least 2 minutes) or intravenous infusion (for 15 minutes) for up to 10 days. Discontinue PANSPED I.V. as soon as the patient can tolerate oral treatment. Switch to an appropriate oral medication within 10 days of starting PANSPED I.V. The recommended dosage for paediatric patients 3 months of age and older is based on age and actual body weight.

CONTRAINDICATION: PANSPED I.V. is contraindicated in patients with known hypersensitivity reactions including anaphylaxis to the formulation or any substituted benzimidazole. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, acute tubulointerstitial nephritis, and urticaria.

WARNINGS & PRECAUTIONS: *Injection Site Reactions*: Thrombophlebitis was associated with the administration of PANSPED I.V. Assess the patient and remove the catheter if clinically indicated. *Severe Cutaneous Adverse Reactions*: Severe cutaneous adverse reactions, including erythema multiforme, Stevens-Johnson syndrome (SJS), and acute generalized exanthematous pustulosis (AGEP) have been reported in association with the use of PPIs. Discontinue PANSPED I.V. at the first signs or symptoms of severe cutaneous adverse reactions or other signs of hypersensitivity. *Hypomagnesemia and Mineral Metabolism:* Hypomagnesemia, symptomatic and asymptomatic, has been reported rarely in patients treated with PPIs for at least three months, and in most cases after a year of therapy. Serious adverse events include tetany, arrhythmias, and seizures.

DRUG INTERACTIONS: Warfarin: Increased prothrombin time in patients receiving PPIs, including pantoprazole, and warfarin concomitantly. This may lead to abnormal bleeding and even death. Clopidogrel: Concomitant administration of pantoprazole and clopidogrel in healthy subjects had no clinically important effect on exposure to the active metabolite of clopidogrel or clopidogrel-induced platelet inhibition. Antiretrovirals: Decreased exposure of some antiretroviral drugs (e.g., rilpivirine atazanavir, and nelfinavir) when used concomitantly with pantoprazole may reduce antiviral effect and promote the development of drug resistance**.**

ADVERSE REACTIONS: *Body as a Whole:* allergic reaction, fever, photosensitivity reaction, facial edema, thrombophlebitis (intravenous only); *Gastrointestinal:* constipation, dry mouth, hepatitis; *Hematologic:* leukopenia (reported in ex-US clinical trials only), thrombocytopenia; *Metabolic/Nutritional:* elevated CPK (creatine phosphokinase), generalized edema, elevated triglycerides, liver function tests abnormal; *Musculoskeletal:* myalgia; *Nervous:* depression, vertigo; *Skin and Appendages:* urticaria, rash, pruritus; *Special Senses:* blurred vision; *Paediatrics*: Adverse reactions reported with single and multiple doses of PANSPED I.V. in 18 hospitalized paediatric patients 1 to 16 years of age were generally like those reported in adults treated with intravenous or oral pantoprazole sodium and in paediatric patients treated with oral sodium in clinical trials; *General disorders and*

administration conditions: asthenia, fatigue, malaise**;** *Immune system disorders*: anaphylaxis (including anaphylactic shock), systemic lupus erythematosus; *Investigations*: weight changes; *Skin and subcutaneous tissue disorders*: severe dermatologic reactions (some fatal), including erythema multiforme, SJS/TEN, DRESS, AGEP, angioedema (Quincke's edema) and cutaneous lupus erythematosus; *Musculoskeletal disorders*: rhabdomyolysis, bone fracture; *Renal and genitourinary disorders*: acute tubulointerstitial nephritis, erectile dysfunction; *Hepatobiliary disorders*: hepatocellular damage leading to jaundice and hepatic failure; *Psychiatric disorder*: hallucinations, confusion, insomnia, somnolence; *Metabolism and nutritional disorders*: hyponatremia, hypomagnesemia, hypocalcaemia, hypokalaemia; *Infections and infestations*: Clostridioides difficile-associated diarrhoea; *Hematologic*: pancytopenia, agranulocytosis; *Nervous*: ageusia, dysgeusia; *Gastrointestinal disorders*: fundic gland polyps.

MARKETED BY:

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(Additional information is available on request)