

CHEPATRON

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

Abbreviated Prescribing information for **CHEPATRON** [Palonosetron Hydrochloride (0.25mg/5ml) Injection] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: 5-HT₃ receptor antagonist with a strong binding affinity for this receptor and little or no affinity for other receptors.

INDICATION: For prevention of nausea/vomiting associated with initial and repeat course of moderately and highly emetogenic cancer chemotherapy.

DOSAGE AND ADMINISTRATION: A single 0.25 mg I.V. dose administered over 30 seconds. Dosing should occur approximately 30 minutes before the start of chemotherapy.

CONTRAINDICATION: Hypersensitivity to the drug or any of its components.

WARNINGS & PRECAUTIONS: Hypersensitivity reactions, including anaphylaxis, serotonin syndrome. Symptoms of serotonin syndrome: mental status changes (e.g. agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, with or without gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea).

DRUG INTERACTIONS: Risk of serotonin syndrome with selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs) when used concomitantly.

ADVERSE REACTIONS: Headache, constipation, non-sustained tachycardia, bradycardia, hypotension, hypertension, myocardial ischemia, extrasystoles, sinus tachycardia, sinus arrhythmia, supraventricular extrasystoles, QT prolongation, allergic dermatitis, rash, motion sickness, tinnitus, eye irritation, amblyopia, dyspepsia, dry mouth, hiccups, flatulence, weakness, fever, hot flash, flu-like syndrome, transient, asymptomatic increases in AST and/or ALT and bilirubin, hyperkalemia, electrolyte fluctuations, hyperglycemia, metabolic acidosis, glycosuria, appetite decrease, anorexia, arthralgia, somnolence, hypersomnia, paresthesia, anxiety, euphoric mood, urinary retention, vein discoloration, vein distention, laryngospasm, and injection site reactions (burning, induration, discomfort and pain).

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

IN/CHEPATRON 0.25mg/Jun-15/01/AbPI
(Additional information is available on request)