

NEXPRO JUNIOR

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory
Only Abbreviated Prescribing information for NEXPRO JUNIOR (Esomeprazole Delayed Release Granules for Oral Suspension 1g) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H⁺/K⁺-ATPase in the gastric parietal cell.

INDICATION: Treatment of Gastroesophageal Reflux Disease (GERD); Risk reduction of NSAID Associated Gastric Ulcer; *H. Pylori* eradication to reduce the risk of duodenal ulcer recurrence; Pathological hypersecretory conditions including Zollinger-Ellison Syndrome (ZES).

DOSAGE AND ADMINISTRATION: Direction for use: The contents of each sachet should be emptied into a container containing 1 tablespoon (15 ml) of water, stir and drink within 30 minutes. The granules must not be chewed or crushed. Do not use carbonated water. **GERD:** The dose varied from 10mg to 40mg for different indication, based on body weight, age and underlined concurrent disease condition. **Children** (Age 1-11 years, weight ≥10kg) 10 to 20mg once daily for 8 weeks; Doses over 1 mg/kg/day have not been studied. **Adults and Adolescent** more than 12 years age 20 to 40mg for 4 weeks. **H. Pylori eradication:** 20mg dose along with amoxicillin and clarithromycin. **ZES:** 40 to 160mg dose (more than 80mg dose should be divided). **NSAID Associated Gastric Ulcer:** 20mg once daily for 4 to 8 weeks.

CONTRAINDICATION: Known hypersensitivity to any component of the formulation or to substituted benzimidazoles. Esomeprazole should not be used concomitantly with nelfinavir.

WARNINGS & PRECAUTIONS: Lowest dose and shortest duration of PPI therapy appropriate to the condition being treated should be used. Caution advisable for Concurrent gastric malignancy, Use with clopidogrel (impaired metabolism), risk of bone fracture (year or long therapy), and hypomagnesemia (3 months to year) may be manifested by seizure, arrhythmia, tetany. Drugs causing hypomagnesemia (digoxin, diuretics etc.), St John's Wort and Rifampin decrease esomeprazole concentrations, Diagnostic investigation for Neuroendocrine Tumors (increased level), Methotrexate (increase level). Caution requires as it may cause atrophic gastritis, and *C. Difficile* associated diarrhea (especially in hospitalized patient).

DRUG INTERACTION: Drugs metabolised by CYP2C19, CYP3A4 increases exposure of esomeprazole.

ADVERSE REACTIONS: Leukopenia, thrombocytopenia, *Immune system disorders:* Rare: Hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock *Metabolism and nutrition disorders:* Rare: Peripheral oedema, Hyponatraemia, *Not known:* Hypomagnesaemia, *Psychiatric disorders:* Insomnia, Agitation, confusion, depression, Aggression, hallucinations, *Nervous system disorders:* Common: Headache, Dizziness, paraesthesia, somnolence, Taste disturbance, *Eye disorders:* Blurred vision. *Ear and labyrinth disorders:* Vertigo. *Respiratory, thoracic and mediastinal disorders:* Bronchospasm. *Gastrointestinal disorders:* Common: Abdominal pain, constipation, diarrhoea, flatulence, Nausea/vomiting, fundic gland polyps (benign), Stomatitis, gastrointestinal candidiasis, *Not known:* Microscopic colitis. *Hepatobiliary disorders:* Increased liver enzymes, Hepatitis with or without jaundice, Hepatic failure, encephalopathy in patients with pre-existing liver disease.

Skin and subcutaneous tissue disorders: Uncommon: Dermatitis, pruritus, rash, urticarial, Alopecia, photosensitivity, Erythema multiform, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), subacute cutaneous lupus erythematosus. *Musculoskeletal and connective tissue disorders: Uncommon:* Fracture of the hip, wrist or spine, *Rare:* Arthralgia, myalgia, Muscular weakness. *Renal and urinary disorders: Very Rare:* Interstitial nephritis; in some patients renal failure has been reported concomitantly, Acute Kidney injury. *Reproductive system and breast disorders: Very rare* Gynaecomastia. *General disorders and administration site conditions: Rare:* Malaise, increased sweating.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

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

IN/NEXPRO JUNIOR/FEB 2015/01/AbPI

(Additional information is available on request)