**NEXPRO IV**

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

Abbreviated Prescribing information for NEXPRO IV (Esomeprazole Sodium Powder for Injection, Lyophilized, Sterile single dose vial) [Please refer the complete prescribing information available at www.torrentpharma.com]

**PHARMACOLOGICAL PROPERTIES**: The active ingredient in NEXPRO I.V. (esomeprazole sodium) is a proton pump inhibitor that inhibits gastric acid secretion.

**INDICATION:** For the treatment of Gastroesophageal Reflux Disease (GERD) with esophagitis (EE) and/or severe symptoms of reflux as an alternative to oral therapy when oral intake is not possible or appropriate.

**DOSAGE AND ADMINISTRATION:** Patient who can't take oral medications may be treated parentally with 20- 40 mg once daily. For reflux oesophagitis: 40 mg once daily. For symptomatic reflux diseases: 20 mg once daily.

**CONTRAINDICATION:** Patients with known hypersensitivity to any component of the formulation or to substituted benzimidazoles.

**WARNINGS & PRECAUTIONS**: Caution required for risk of concomitant gastric malignancy, Atrophic Gastritis, *Clostridium difficile* associated diarrhea, Bone Fracture and Hypomagnesemia.

**DRUG INTERACTION:** Warfarin**:** changes in prothrombin measures. Diazepam: 45% decrease in clearance of diazepam. Cilostazol: expected to increase concentrations of cilostazol. Inhibitor of CYP2C19 and CYP3A4, such as voriconazole: may result in more than doubling of the esomeprazole exposure. Rifampin OR St John's Wort: decrease esomeprazole serum levels. Absorption of drugs such as ketoconazole, atazanavir, iron salts, and erlotinib can decrease, while the absorption of drugs such as digoxin can increase during treatment with esomeprazole. Atazanavir: not recommended, decrease atazanavir plasma concentrations. Tacrolimus: increase the serum levels of tacrolimus. Methotrexate: elevate and prolong serum levels of methotrexate. With Diagnostic Investigations for Neuroendocrine Tumors: Serum chromogranin A (CgA) levels increase which may cause false positive results.

**ADVERSE REACTIONS:** Headache, diarrhea, nausea, flatulence, abdominal pain, constipation, dry mouth. Abdomen enlarged, Allergic reaction, Asthenia, Back/Chest pain, Facial/ peripheral edema, Hot flushes, Fatigue, Fever, Generalized edema, Malaise, Rigors, Hypertension, Tachycardia, Flushing, Goiter, Bowel irregularity, Dyspepsia, Dysphagia, Dysplasia GI, Epigastric pain, Esophageal disorder, Frequent stools, Gastroenteritis, GI hemorrhage, Mouth disorder, Pharynx disorder, Rectal disorder, Tongue disorder, Tongue edema, Ulcerative stomatitis, Vomiting; Earache, Tinnitus; Anemia, Epistaxis, Hepatic function abnormal, Glycosuria, Hyperuricemia, Vitamin B12 deficiency, weight changes, Arthralgia, Arthritis aggravated, Arthropathy, Camps, Fibromyalgia syndrome, Hernia, Polymyalgia rheumatica; Menstrual disorder, Acne, Angioedema, Dermatitis, Otitis media, Albuminuria, Cystitis, Conjunctivitis, Vision abnormal, Agranulocytosis, Pancytopenia, Hepatic failure, Anaphylactic reaction, Hypomagnesemia, Acute kidney injury, Aggression, interstitial nephritis, Stevens-Johnson syndrome, Toxic epidermal necrolysis.

**MARKETED BY:**

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(Additional information is available on request)