

NEXPRO L

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

Abbreviated Prescribing information for Nexpro L (Esomeprazole DR and Levosulpiride ER Capsules) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: *Esomeprazole* is a proton pump inhibitor (PPI) that suppresses gastric acid secretion by specific inhibition of the H⁺/K⁺-ATPase in the gastric parietal cell. *Levosulpiride* is selective blocks D2 receptors at the submucosal and myenteric plexus peripheral level.

INDICATIONS: For short term therapy of Gastroesophageal Reflux Disease (GERD) in patients who do not respond to PPI alone.

DOSAGE AND ADMINISTRATION: One capsule of Nexpro L should be taken orally with water one hour before meal.

CONTRAINDICATIONS: Known hypersensitivity to esomeprazole, to substituted benzimidazoles, levosulpiride or to any component of the formulation. In patients of pheochromocytoma, epilepsy, manic states and having concomitant prolactin dependent tumors. It is also contraindicated in pregnancy, lactation and patients taking levodopa concomitantly.

WARNINGS & PRECAUTIONS: Caution required for Concurrent Gastric Malignancy, atrophic gastritis, bone fracture, hypomagnesemia, while with concomitant use of St John's Wort or Rifampin and for Interactions with Investigations for Neuroendocrine Tumors. *Levosulpiride:* Cautions should be taken for Neuroleptic malignant syndrome, prolongations of QTc interval or factors that may predispose QTc interval prolongation, in the patients taking antipsychotic medication, having cardiac insufficiency, cerebrovascular events. It may cause drowsiness, especially at higher doses, thus patients should be advised to exercise caution when driving or operating machinery.

DRUG INTERACTIONS: *Esomeprazole:* Antiretroviral therapy, interaction with drugs for which gastric pH can affect bioavailability, co-administration of esomeprazole alters the level of diazepam, clopidogrel, cilostazol, voriconazole, inducers of CYP2C19 or CYP3A4 or both, tacrolimus, clarithromycin, amoxicillin and methotrexate. Also esomeprazole may increase chromogranin a levels. *Levosulpiride:* It can interact with drugs like centrally acting drugs like CNS depressants, lithium, anti-hypertensives, electrolyte imbalance inducing medications, antiarrhythmic agents, antacids or sucralfate and ropinorole etc.

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, *Very rare:* Parkinsonism, Dyskinesia, Tremor, Dystonia, Psychomotor agitation, Disorders of the autonomic nervous system. *Not known:* Neuroleptic Malignant Syndrome. *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. *Cardiac disorders: Rare:* QT prolongation, Ventricular arrhythmias such as torsades de pointes, Ventricular tachycardia, Ventricular fibrillation, Cardiac arrest. *Very rare:* Sudden death. *Vascular disorders: Not known:* Thromboembolism (including cases of pulmonary embolism and deep venous thrombosis). *Pregnancy, puerperium and perinatal conditions: Not known:* Neonatal withdrawal syndrome, Extrapyramidal symptoms. *Investigations: Not known:* Hyperprolactinaemia.

MARKETED BY



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(Additional information is available on request)