

NEXPRO RD

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

Abbreviated Prescribing information for NEXPRO RD (Esomeprazole Magnesium 20 mg/40 mg and Domperidone 30 mg Sustained Release Capsules) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Esomeprazole: It is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H⁺/K⁺-ATPase. **Domperidone:** It is a dopamine antagonist with anti-emetic properties.

INDICATION: For the relief of post-prandial symptoms of fullness, nausea, epigastric bloating and belching accompanied by epigastric discomfort and heartburn, not responding to omeprazole alone.

DOSAGE AND ADMINISTRATION: One capsule twice daily. Maximum allowed dose for omeprazole is 40mg and for domperidone is 80mg.

CONTRAINDICATION: Esomeprazole: in patients with known hypersensitivity to any component of the formulation. Sodium bicarbonate is contraindicated in patients with metabolic alkalosis and hypocalcemia. **Domperidone:** Known hypersensitivity to domperidone or any of the excipients, Prolactin-releasing pituitary tumour, Gastro-intestinal haemorrhage, Mechanical obstruction or perforation, Hepatic and/or renal impairment.

WARNINGS & PRECAUTIONS: Esomeprazole: Caution require for Concurrent Gastric Malignancy, Atrophic Gastritis, Clostridium difficile associated diarrhea, Bone Fracture, Hypomagnesemia. St John's Wort or Rifampin use: can substantially decrease esomeprazole concentrations. Interactions with Diagnostic Investigations for Neuroendocrine Tumors: can increase Serum chromogranin A (CgA) levels which may cause false positive results. Methotrexate: elevate and prolong serum levels of methotrexate.

Domperidone: Patients who find they have post-prandial symptoms, nausea and vomiting that persist, and are having to take domperidone continuously for more than 2 weeks should be referred to their doctor. Use with Potent CYP3A4 Inhibitors: prolong the QTc interval, should be avoided. Cardiac effects: may be associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death. Use with drugs which prolong QTc intervals requires that caution be exercised.

DRUG INTERACTION: Esomeprazole: Atazanavir, and nelfinavir: their plasma concentrations may be decreased. Saquinavir: serum levels may be elevated. Drugs that decrease the intragastric acidity, the 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. Warfarin: changes in prothrombin measures. Diazepam: 45% decrease in clearance of diazepam. Clopidogrel: reduce platelet inhibition. Cilostazol: expected to increase concentrations of cilostazol. Voriconazole: may result in more than doubling of the esomeprazole exposure. Tacrolimus: increase the serum levels of tacrolimus. Clarithromycin: increases in the plasma levels of esomeprazole and 14-hydroxycarithromycin. **Domperidone:** Anticholinergic drugs: may antagonise the anti-dyspeptic effect of domperidone. ketoconazole or erythromycin: marked inhibition of domperidone's CYP3 A4 and can prolong QTc interval.

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, Esophageal disorder, Gastroenteritis, GI hemorrhage, Mouth disorder, Pharynx disorder, Rectal disorder, Tongue disorder, Ulcerative stomatitis, Vomiting; Earache, Tinnitus; Anemia, Epistaxis, Hepatic function abnormal, Glycosuria, Hyperuricemia, Vitamin B12 deficiency, weight changes, Arthralgia, Arthropathy, Camps, Fibromyalgia syndrome, Hernia, Polymyalgia rheumatica; Menstrual disorder, Acne, Angioedema, Dermatitis, Otitis media, Albuminuria, Cystitis, Conjunctivitis, Oculogyric crisis, Vision abnormal, duodenitis, esophageal ulceration, Barrett's esophagus, loss of libido, Anxiety, Somnolence, Rash, Pruritus, Galactorrhoea, Breast pain, Breast tenderness, Stevens- Johnson syndrome, toxic epidermal necrolysis and acute kidney injury.

MARKETED BY:



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(Additional information is available on request)