NEXPRO 80

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

Abbreviated Prescribing information for **NEXPRO 80**

(Esomeprazole Dual-release Gastro-resistant Tablets 80 mg) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action:

Esomeprazole is a weak base and is concentrated and converted to the active form in the highly acidic environment of the secretory canaliculi of the parietal cell, where it inhibits the enzyme H+ K+ ATPase the acid pump and inhibits both basal and stimulated acid secretion.

INDICATIONS: It is indicated for the treatment of moderate to severe refractory gastro-esophageal reflux disease (GERD) for 4 weeks only

DOSAGE AND ADMINISTRATION: As directed by the Physician. Tablets should be taken orally.

CONTRAINDICATION: Hypersensitivity to the active substance, to substituted benzimidazoles or to any of the excipients. Esomeprazole should not be used concomitantly with nelfinavir.

WARNINGS & PRECAUTIONS:

In the presence of any alarm symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melaena) and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment with NEXPRO may alleviate symptoms and delay diagnosis.

Long term use: Patients on long-term treatment (particularly those treated for more than a year) should be kept under regular surveillance. ***On demand treatment***: Patients on on-demand treatment should be instructed to contact their physician if their symptoms change in character. ***Helicobacter pylori eradication***: When prescribing esomeprazole for eradication of Helicobacter pylori, possible drug interactions for all components in the triple therapy should be considered. Clarithromycin is a potent inhibitor of CYP3A4 and hence contraindications and interactions for clarithromycin should be considered when the triple therapy is used in patients concurrently taking other drugs metabolised via CYP3A4 such as cisapride. ***Gastrointestinal infections***:Treatment with proton pump inhibitors may lead to slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter. ***Absorption of vitamin B12:*** Esomeprazole, as all acid-blocking medicines, may reduce the absorption of vitamin B12 (cyanocobalamin) due to hypo- or achlorhydria. This should be considered in patients with reduced body stores or risk factors for reduced vitamin B12 absorption on long-term therapy. ***Hypomagnesaemia:*** Severe hypomagnesaemia has been reported in patients treated with proton pump inhibitors (PPIs) like esomeprazole for at least three months, and in most cases for a year. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia can occur but they may begin insidiously. ***Risk of fracture***: Proton pump inhibitors, especially if used in high doses and over long durations (>1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in presence of other recognised risk factors. ***Subacute cutaneous lupus erythematosus (SCLE)***: Proton pump inhibitors are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping NEXPRO. ***Combination with other medicinal_products***: Co-

administration of esomeprazole with atazanavir is not recommended. If the combination of atazanavir with a proton pump inhibitor is judged unavoidable, close clinical monitoring is recommended in combination with an increase in the dose of atazanavir to 400 mg with 100 mg of ritonavir; esomeprazole 20 mg should not be exceeded. ***Interference with laboratory tests***: Increased Chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, esomeprazole treatment should be stopped for at least 5 days before CgA measurements.

DRUG INTERACTIONS: ***Protease inhibitors:*** Omeprazole has been reported to interact with some protease inhibitors. Other possible interaction mechanisms are via inhibition of CYP2C19. ***Methotrexate***: When given together with PPIs, methotrexate levels have been reported to increase in some patients. ***Tacrolimus***: Concomitant administration of esomeprazole has been reported to increase the serum levels of tacrolimus. ***Medicinal products with pH dependent absorption:*** Gastric acid suppression during treatment with esomeprazole. ***Medicinal products metabolised by CYP2C19:*** Esomeprazole inhibits CYP2C19, the major esomeprazole-metabolising enzyme. Thus, when esomeprazole is combined with drugs metabolised by CYP2C19, such as diazepam, citalopram, imipramine, clomipramine, phenytoin etc. ***Diazepam****:* Concomitant administration of 30 mg esomeprazole resulted in a 45% decrease in clearance of the CYP2C19 substrate diazepam. ***Phenytoin:*** Concomitant administration of 80 mg esomeprazole resulted in a 13% increase in trough plasma levels of phenytoin in epileptic patients. ***Voriconazole:*** Omeprazole (40 mg once daily) increased voriconazole (a CYP2C19 substrate) C_{max} and AUC by 15% and 41%, respectively. Medicinal products which induce CYP2C19 and/or CYP3A4, Naproxen or rofecoxib, Amoxicillin and quinidine, Clopidogrel, Warfarin, Cisapride, Cilostazol, Medicinal products which inhibit CYP2C19 and/or CYP3A4.

ADVERSE REACTIONS: ***Summary of the safety profile:*** Headache, abdominal pain, diarrhoea and nausea are among those adverse reactions that have been most commonly reported in clinical trials (and also from post-marketing use). ***Bloodand lymphatic system disorders:*** Leukopenia, thrombocytopenia, Leukopenia, thrombocytopenia, Hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock. ***Immune system disorders:*** Hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock. ***Metabolism and nutrition disorders:*** Peripheral oedema, Hyponatraemia, Hypomagnesaemia; severe hypomagnesaemia can correlate with hypocalcaemia. Hypomagnesaemia may also be associated with hypokalaemia. ***Psychiatric disorders:*** Insomnia, Agitation, confusion, depression, Aggression, hallucinations, ***Nervous system disorders:*** Headache, Dizziness, paraesthesia, somnolence, Taste disturbance. ***Eye disorders***: Blurred vision, ***Ear and labyrinth disorders:*** Vertigo, Respiratory. ***thoracic and mediastinal disorders:*** Bronchospasm, ***Gastrointestinal disorders:*** Abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting, fundic gland polyps (benign), Dry mouth, Stomatitis, gastrointestinal candidiasis, 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:*** Dermatitis, pruritus, rash, urticarial, Alopecia, photosensitivity, Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), Subacute cutaneous lupus erythematosus, ***Musculoskeletal and connective tissue disorders:*** Fracture of the hip, wrist or spine, Arthralgia, myalgia, Muscular weakness. ***Renal and urinary disorders:*** Interstitial nephritis; in some patients renal failure has been reported concomitantly, Acute kidney injury. ***Reproductive system and breast disorders***: Gynaecomastia. ***General disorders and administrationsite conditions:*** Malaise, increased sweating.

MARKETED BY:

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