

## NEXPRO 20 and 40

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

Abbreviated Prescribing information for NEXPRO 20 and 40(Esomeprazole magnesium trihydrate)  
[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### 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.

**Indication:** For the treatment of erosive reflux oesophagitis, prevention of release of acid and helps in eradication of H. pylori associated peptic ulcer.

**DOSAGE AND ADMINISTRATION:** The tablets should be swallowed whole with liquid. The tablets should not be chewed or crushed or As directed by physician.

**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, On demand treatment, Helicobacter pylori eradication, Gastrointestinal infections, Absorption of vitamin B12, Hypomagnesaemia, Risk of fracture, Subacute cutaneous lupus erythematosus (SCLE), Combination with other medicinal products: atazanavir, clopidogrel. Sucrose, Interference with laboratory tests, Sodium content.

**DRUG INTERACTION:** Effects of esomeprazole on the pharmacokinetics of other drugs  
Protease inhibitors: Omeprazole, atazanavir, saquinavir, ritonavir. Methotrexate, Tacrolimus, Medicinal products with pH dependent absorption:ketoconazole, itraconazole and erlotinib. Medicinal products metabolised by CYP2C19: Diazepam, Phenytoin, Voriconazole, Cilostazol, Cisapride, Warfarin, Clopidogrel. Investigated medicinal products with no clinically relevant interaction: Amoxicillin and quinidine, Naproxen or rofecoxib, Effects of other medicinal products on the pharmacokinetics of esomeprazole, Medicinal products which inhibit CYP2C19 and/or CYP3A4, Medicinal products which induce CYP2C19 and/or CYP3A4, Paediatric population.

**ADVERSE REACTIONS:** Headache, diarrhoea, stomach pain, constipation, wind (flatulence), nausea, vomiting, Benign polyps in the stomach, Swelling of the feet and ankles, Disturbed sleep (insomnia), Dizziness, tingling feelings such as “pins and needles”, feeling sleepy, Spinning feeling (vertigo), Dry mouth, Changes in blood tests that check how the liver is working, Skin rash, lumpy rash (hives) and itchy skin, Fracture of the hip, wrist or spine, Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramp, Feeling agitated, confused or depressed, Taste changes, Eyesight problems such as blurred vision, Suddenly feeling wheezy or short of breath (bronchospasm), An inflammation of the inside of the mouth, An infection called “thrush” which can affect the gut and is caused by a fungus, Liver problems, including jaundice which can cause yellow

skin, dark urine, and tiredness, Hair loss (alopecia), Skin rash on exposure to sunshine, Joint pains (arthralgia) or muscle pains (myalgia), Generally feeling unwell and lacking energy, Increased sweating, Changes in blood count including agranulocytosis (lack of white blood cells), Aggression, Seeing, feeling or hearing things that are not there (hallucinations), Severe liver problems leading to liver failure and inflammation of the brain, Muscle weakness, Severe kidney problems, Acute kidney injury, Enlarged breasts in men.

**Manufactured by:**

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**NEXPRO 20 mg, 40 mg/APR-21/02/ABPI**

(Additional information is available on request)

