

NEXPRO FAST

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.
Abbreviated Prescribing information for NEXPRO FAST (Esomeprazole Tablets (With sodium bicarbonate as buffer))

[Please refer the complete prescribing information available at 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.

DOSAGE AND ADMINISTRATION: One tablet once daily 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 esomeprazole may alleviate symptoms and delay diagnosis. When prescribing esomeprazole for eradication of *Helicobacter pylori*, possible drug interactions for all components in the triple therapy should be considered. It increases risk of gastrointestinal infections such as *Salmonella* and *Campylobacter*, reduce the absorption of vitamin B₁₂, Severe hypomagnesaemia has been reported. It increases risk of fracture and subacute cutaneous lupus erythematosus (SCLE). Co-administration of esomeprazole with atazanavir is not recommended. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

DRUG INTERACTION: Effects of esomeprazole on the pharmacokinetics of other drugs: Interacts with protease inhibitors, methotrexate, tacrolimus. With medicinal products: with pH dependent absorption, which are metabolised by CYP2C19, when concomitantly administered with diazepam, phenytoin, voriconazole, cilostazol, cisapride, warfarin, clopidogrel. Effects of other medicinal products on the pharmacokinetics of esomeprazole: Medicinal products, which inhibit CYP2C19 and/or CYP3A4 (such as clarithromycin, voriconazole) and which induce CYP2C19 and/or CYP3A4 (such as rifampicin and St. John's wort).

ADVERSE REACTIONS: Leukopenia, thrombocytopenia, Agranulocytosis, pancytopenia, Hypersensitivity reactions, Peripheral oedema, Hyponatraemia, Hypomagnesaemia, Insomnia, Agitation, confusion, depression, Aggression, hallucinations, Headache, Dizziness, paraesthesia, somnolence, Taste disturbance, Blurred vision, Vertigo, Bronchospasm, Abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting, fundic gland polyps (benign), Dry mouth, Stomatitis, gastrointestinal candidiasis, Microscopic colitis, Increased liver enzymes, Hepatitis with or without jaundice, Dermatitis, pruritus, rash, urticarial, Alopecia, photosensitivity, Fracture of the hip, wrist or spine, Subacute cutaneous lupus erythematosus, Arthralgia, myalgia, Interstitial nephritis, acute kidney injury, Gynaecomastia, Malaise, increased sweating.

Marketed BY:

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OR

Manufactured by:
Ravenbhel Biotech
EPIP, SIDCO, Kartholi, Bari-Brahmana, Jammu-181133.

IN/NEXPRO FAST 20, 40 mg/OCT-20/06/ABPI

(Additional information is available on request)