

## NEXPRO IT

**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only**  
Abbreviated Prescribing information for NEXPRO IT (Enteric coated Esomeprazole 40 mg and Itopride Hydrochloride sustained release 150 mg capsules) [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES: *Esomeprazole magnesium trihydrate*:** 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<sup>+</sup>K<sup>+</sup>-ATPase – the acid pump and inhibits both basal and stimulated acid secretion.

***Itopride hydrochloride*:** Itopride hydrochloride activates gastrointestinal propulsive motility due to its dopamine D<sub>2</sub> antagonizing activity and acetylcholinesterase inhibitory activity. Itopride activates acetylcholine release and inhibits its degradation.

**DOSAGE AND ADMINISTRATION:** Dose: As directed by Physician

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

Nexpro IT must not be used in patients in whom increased gastrointestinal motility could be harmful, e.g. in patients with gastrointestinal haemorrhage, mechanical obstruction or perforation.

**WARNINGS & PRECAUTIONS: *Esomeprazole*:** Long term use, On demand treatment: Helicobacter pylori eradication, Gastrointestinal infections, Absorption of vitamin B<sub>12</sub>, Hypomagnesaemia, Risk of fracture, Subacute cutaneous lupus erythematosus (SCLE), Combination with other medicinal products: CYP2C19 inhibitor and 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. ***Itopride hydrochloride*:** Itopride potentiates acetylcholine action and can induce side anticholinergic effects. Data on long-term use are not available.

**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. ***Itopride hydrochloride*:** Metabolic interactions are not expected since itopride is primarily metabolized by flavine monooxygenase and not by CYP450. No changes in protein binding have been seen with coadministration of warfarin, diazepam, diclofenac sodium, ticlopidine hydrochloride, nifedipine, and nicardipine hydrochloride. Since itopride has gastrokinetic effects it could influence the absorption of concomitantly orally administered drugs. Particular caution should be taken with drugs with a narrow therapeutic index, sustained release or enteric-coated formulations. Anti-ulcer drugs like cimetidine, ranitidine, teprenone and cetraxate do not affect the prokinetic action of itopride. Anticholinergic may reduce the action of itopride..

**ADVERSE REACTIONS:** Dizziness, headache, and tremor, Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence), increased, saliva, and nausea. Feeling sick (nausea) or being sick (vomiting). Benign polyps in the stomach, Decrease Platelet count, Increased milk production, Excessive development of the male breasts, Jaundice, Rash, redness, and itching, Liver dysfunctions , Acute kidney injury, 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.

**MARKETED BY:**



**TORRENT PHARMACEUTICALS LTD.**

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(Additional information is available on request)