

## NEXPRO HP KIT

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

Abbreviated Prescribing information for NEXPRO HP KIT (Combikit of Clarithromycin Tablets I.P.,  
Esomeprazole Tablets I.P. And Amoxicillin Tablets U.S.P.)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** **Clarithromycin:** Clarithromycin has bactericidal activity against several bacterial strains. The organisms include Hemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus agalactiae, Moraxella (Branhamella) catarrhalis, Neisseria gonorrhoeae, H. pylori and Campylobacter spp. **Esomeprazole:** 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. **Amoxicillin:** Amoxicillin is semisynthetic penicillin (beta-lactam antibiotic) that inhibits one or more enzymes (often referred to as penicillin-binding proteins, PBPs) in the biosynthetic pathway of bactericidal peptidoglycan, which is an integral structural component of the bacterial cell wall. Inhibition of peptidoglycan synthesis leads to weakening of the cell wall, which is usually followed by cell lysis and death.

**INDICATIONS:** It is indication for healing of duodenal ulcer associated with Helicobacter pylori and eradication of helicobacter pylori in patients with active or healed peptic ulcer.

**DOSAGE AND ADMINISTRATION:** **Dose:** The combipack contains two tablets of clarithromycin (500 mg), two tablets of esomeprazole (40 mg), and two tablets of amoxicillin (1000mg). One pack is for 1 day of treatment. From this specially designed pack, one tablet of clarithromycin, one tablet of esomeprazole, and one tablet of amoxicillin are to be taken in the morning and similarly one each in the evening. The duration of therapy recommended is for 7 days or as directed by the Physician. Renal and Hepatic Impairment: Caution should be exercised while administering the combipack of clarithromycin, esomeprazole and amoxicillin to patients with renal and hepatic impairment. **Method of administration:** For oral administration only.

**CONTRAINDICATION:** Contraindicated in patients with known severe hypersensitivity to any component of the formulation. **Clarithromycin:** (a) Patients with history of QT prolongation or ventricular cardiac arrhythmia, including torsades de pointes. (b) Concomitant administration of clarithromycin and colchicine is contraindicated in patients with renal or hepatic impairment. (c) Clarithromycin should not be used concomitantly with HMG-CoA reductase inhibitors (statins) that are extensively metabolized by CYP3A4 (lovastatin or simvastatin). (d) Patients with hypokalaemia. (e) In patients who suffer from severe hepatic failure in combination with renal impairment. (f) Concomitant administration of Clarithromycin and any of the following drugs is contraindicated: Cisapride, pimozone, astemizole, terfenadine, and ergotamine or dihydroergotamine. **Esomeprazole:** (a) Esomeprazole should not be used concomitantly with nelfinavi. **Amoxicillin** History of a severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam agent (e.g. a cephalosporin, carbapenem or monobactam).

**WARNINGS & PRECAUTIONS:** Do not take Clarithromycin, Esomeprazole & Amoxicillin Tablets: (a) if you have an allergy to: any medicines containing esomeprazole, amoxicillin or clarithromycin. Any other similar medicines such as proton pump inhibitors, penicillins, cephalosporins or macrolide antibiotics. (b) If you are taking any of the following medicines: ergotamine, cisapride, pimozone, dihydroergotamine, astemizole, terfenadine, cilostazol, atazanavir, colchicine, simvastatin, lovastatin, ticagrelor, ranolazine, colchicine, oral midazolam, domperidone. (c) If you have a history of heart conditions such as QT prolongation or ventricular cardiac arrhythmia. (d) If you have low potassium levels. (e) If you have both liver and kidney problems.

**DRUG INTERACTIONS:** **Clarithromycin:** The use of the following drugs is strictly contraindicated due to the potential for severe drug interaction effects: Cisapride, pimozone, astemizole and terfenadine, Ergot alkaloids, Oral Midazolam, HMG-CoA Reductase Inhibitors (statins), Effects of Other Medicinal Products on Clarithromycin, Efavirenz, nevirapine, rifampicin, rifabutin and rifapentine, Etravirine, Fluconazole. Clarithromycin shows drug interaction with: CYP3A isozyme (alprazolam, astemizole etc), Antiarrhythmics: quinidine or disopyramide, Oral hypoglycemic agents/Insulin: nateglinide, and repaglinide, Sildenafil, tadalafil and vardenafil, Theophylline, carbamazepine, Colchicine, Digoxin, Zidovudine, Phenytoin, Valproate, Atazanavir, Calcium Channel Blockers (e.g. verapamil, amlodipine, diltiazem), Itraconazole, Saquinavir. **Esomeprazole:** Esomeprazole shows drug interaction with: Protease inhibitors (Omeprazole), atazanavir, nelfinavir, Saquinavir, Methotrexate, Tacrolimus,

Medicinal products with pH dependent absorption, Diazepam, Phenytoin, Voriconazole, Cilostazol, Cisapride, Warfarin, Clopidogrel. **Amoxicillin:** Amoxicillin shows drug interaction with: Oral anticoagulants, Probenecid, Allopurinol, Tetracyclines, and Methotrexate.

**ADVERSE REACTIONS:** Diarrhoea, Nausea, Vomiting, Headache, Dizziness, Constipation, Loss of appetite, Stomach pain (e.g. cramps), Wind, Dryness of the mouth or other body cavities, Soreness of mouth or tongue, "Pins and needles", Metallic taste or other change in taste or smell, Chills, Fatigue, Excessive burping, Muscle pain or weakness, Increase in breast size (males), Fever, Changes in sleep patterns, Mood changes, Hallucinations, Confusion or depression, Change in sexual function, Blurred vision, Hearing disturbances, Hair loss, Bleeding or bruising more easily than normal, Signs of frequent infections such as fever, Severe chills, Sore throat or mouth ulcers, Skin rash, Blood in urine, Tremor, Convulsions or fits, Overgrowth of yeast infections (thrush), Fainting, Irregular heartbeat, Yellowing of the eyes or skin, Shortness of breath, Wheezing or difficulty breathing, Swelling of the face, lips, tongue or other parts of the body, Chest pain, Severe skin reaction which may include rash, Itching, Redness, Blistering or peeling of the skin, Signs of liver inflammation including yellowing of the skin or eyes, Skin reaction, especially in sun-exposed areas with joint pain.

**MARKETED BY:**

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**IN/NEXPRO HP KIT 500, 40, 750mg/MAR-2026/05/ABPI**

(Additional information is available on request)