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 (Combipack of Clarithromycin 500mg Tablets, Esomeprazole 40mg Tablets and Amoxicillin 750mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: ***Amoxicillin:*** Amoxicillin is a semisynthetic penicillin (beta-lactam antibiotic) that inhibits one or more enzymes (often referred to as penicillin-binding proteins, PBPs) in the biosynthetic pathway of bacterial 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. Amoxicillin is susceptible to degradation by beta-lactamases produced by resistant bacteria and therefore the spectrum of activity of amoxicillin alone does not include organisms which produce these enzymes. ***Clarithromycin:*** Clarithromycin is a semi-synthetic derivative of erythromycin. It exerts its antibacterial action by inhibiting the intracellular protein synthesis of susceptible bacteria. It selectively binds to the 50s ribosomal sub-unit of susceptible bacteria and suppresses protein synthesis. The minimum inhibitory concentrations (MICs) of clarithromycin are generally two- fold lower than the MICs of erythromycin. The 14-hydroxy metabolite of clarithromycin also has antimicrobial activity. The MICs of this metabolite are equal or twofold higher than the MICs of the parent compound, except for *Haemophilus influenzae* where the 14-hydroxy metabolite is two-fold more active than the parent compound. ***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 K -ATPase – the acid pump and inhibits both basal and stimulated acid secretion.

INDICATION: It is indicated for healing of duodenal ulcer associated with H.Pylori and eradication of H.Pylori in patients with active or healed peptic ulcer.

DOSAGE AND ADMINISTRATION: Recommended dosage is one tablet of each clarithromycin, esomeprazole and amoxicillin twice daily for 7 days. Dosage modification is required for clarithromycin and amoxicillin in patients with renal impairment. Esomeprazole tablets should be swallowed whole with liquid. The tablets should not be chewed or crushed. **CONTRAINDICATION:** ***Amoxicillin:*** Hypersensitivity to the active substance, to any of the penicillins or to any of the excipients. ***Clarithromycin:*** is contra-indicated in patients with known hypersensitivity to macrolide antibiotic drugs or any of the excipients. ***Esomeprazole:*** Hypersensitivity to the active substance, to substituted benzimidazoles or to any of the excipients. Esomeprazole should not be used concomitantly with nelfinavir.

WARNINGS & PRECAUTIONS: ***Amoxicillin:*** Before initiating therapy with amoxicillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other beta-lactam agents. Convulsions, Renal impairment, Skin reactions, Jarisch-Herxheimer reaction, Anticoagulants. **Clarithromycin:** Clarithromycin is principally excreted by the liver and kidney. Caution should be exercised in administering this antibiotic to patients with impaired hepatic function and moderate to severe renal impairment. ***Esomeprazole:*** 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. Helicobacter pylori eradication, Gastrointestinal infections, Absorption of vitamin B12, Hypomagnesaemia, Subacute cutaneous lupus erythematosus (SCLE), Interference with laboratory tests.

DRUG INTERACTION: ***Amoxicillin:*** Probenecid, Allopurinol, Tetracyclines, Oral anticoagulants, Methotrexate. ***Clarithromycin:*** Cisapride, pimozide, astemizole and terfenadine,

Ergotamine/dihydroergotamine, HMG-CoA reductase inhibitors, Efavirenz, nevirapine, rifampicin, rifabutin and rifapentine, Etravirine, Fluconazole, Ritonavir, CYP3A-based interactions, Antiarrhythmics, Theophylline, carbamazepine, Tolterodine, Omeprazole, Colchicine, Digoxin, Atazanavir, Itraconazole, Saquinavir, Verapamil. ***Esomeprazole:*** Protease inhibitors, Methotrexate, Tacrolimus, Medicinal products with pH dependent absorption, Diazepam, Phenytoin, Voriconazole

Cisapride, Warfarin, Clopidogrel, Naproxen or rofecoxib, Medicinal products which inhibit CYP2C19 and/or CYP3A4.

ADVERSE REACTIONS*:* ***Amoxicillin:*** Mucocutaneous candidiasis, Reversible leucopenia, Prolongation of bleeding time and prothrombin time. Severe allergic reactions, Jarisch-Herxheimer reaction, Hyperkinesia, dizziness and convulsions, Diarrhoea and nausea, Vomiting, Antibiotic associated colitis. Black hairy tongue, Superficial tooth discolouration , Hepatitis and cholestatic jaundice, Skin rash, Urticaria and pruritus, Skin reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis, acute generalised exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS). Interstitial nephritis Crystalluria. ***Clarithromycin:*** cellulitis, gastroenteritis, candidiasis, infection, vaginal infection, Pseudomembranou s colitis, leukopenia, agranulocytosis, Anaphylactoid reaction, psychiatric disorder, Anxiety, anorexia, Hypoglycaemia, vasodilation, Heamorrhag, Asthma, Ventricular tachycardia, Cardiac arrest, Esophagitis, gastrooseophageal reflux, gastritis, pancreatitis tongue discolouration, tooth discolouration, fatal hepatic failure, hepatitis, dry skin, pruritus, urticaria, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms (DRESS). Abnormal albumin globulin ratio. ***Esomeprazole:*** Leukopenia, thrombocytopenia, Hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock. 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), Stomatitis, gastrointestinal candidiasis, Microscopic colitis. Increased liver enzymes, Hepatitis with or without jaundice, Hepatic failure, encephalopathy in patients with pre-existing liver disease. Dermatitis, pruritus, rash, urticarial, Alopecia, photosensitivity, Erythema multiform, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), subacute cutaneous lupus erythematosus. Fracture of the hip, wrist or spine, Arthralgia, myalgia, Muscular weakness. Interstitial nephritis; in some patients renal failure has been reported concomitantly, Acute Kidney injury. Gynaecomastia. Malaise, increased sweating.

MARKETED BY:

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(Additional information is available on request)