SUMMARY OF PRODUCT CHARACTERISTICS

3D KIT H. Pylori Kit (Amoxicillin 1000 mg + Levofloxacin 500 mg + Rabeprazole 20 mg)

1. NAME OF THE MEDICINAL PRODUCT

3D KIT H. Pylori Kit

Each kit contains: Amoxicillin Tablets 1000 mg + Levofloxacin Tablets 500 mg + Rabeprazole Tablets 20 mg.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Amoxicillin Tablets 1000 mg: Each film-coated tablet contains amoxicillin trihydrate BP equivalent to amoxicillin 1000 mg.

Levofloxacin Tablets 500 mg: Each film-coated tablet contains levofloxacin hemihydrate USP equivalent to levofloxacin 500 mg.

Rabeprazole Tablets 20 mg: Each enteric-coated tablet contains rabeprazole sodium BP equivalent to rabeprazole 20 mg.

Excipients with known effect:

Levofloxacin tablets contain sunset yellow (as Sunset Yellow Supra) as a colouring agent. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Amoxicillin 1000 mg: Film-coated tablet.

Levofloxacin 500 mg: Film-coated tablet.

Rabeprazole 20 mg: Enteric-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

3D KIT is indicated for the eradication of Helicobacter pylori in adults with active chronic gastritis, duodenal ulcer and gastric ulcer.

4.2 Posology and method of administration

Adults

3D KIT contains 7 one-day kits to be taken over 7 consecutive days. Each one-day kit contains a morning pack and an evening pack. Both the morning and evening packs contain 1 tablet of Amoxicillin 1000 mg, 1 tablet of Levofloxacin 500 mg and 1 tablet of Rabeprazole 20 mg.

The recommended therapy is 7–14 days as per physician's advice. Before prescribing levofloxacin-containing H. pylori eradication regimens, local/national resistance patterns for H. pylori should be considered.

Hepatic impairment

Not recommended for use in patients with severe hepatic impairment (see sections 4.3 and 4.4).

Renal impairment

Levofloxacin and amoxicillin are primarily renally excreted. Dose adjustment of levofloxacin is required in patients with renal impairment (see levofloxacin full prescribing information). This fixed-dose combination kit may not be appropriate in patients with significant renal impairment.

Method of administration

Oral. Levofloxacin and amoxicillin may be taken with or without food. Rabeprazole tablets should be swallowed whole, not chewed or crushed.

4.3 Contraindications

Hypersensitivity to any active substance or to any of the excipients listed in section 6.1.

Amoxicillin specific:

- History of a severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam agent (e.g. cephalosporin, carbapenem or monobactam).
- History of jaundice/hepatic impairment due to amoxicillin.

Levofloxacin specific:

- Hypersensitivity to other quinolones.
- Patients with epilepsy.
- Patients with a history of tendon disorders related to fluoroquinolone administration.
- Children or growing adolescents.
- During pregnancy.
- In breast-feeding women.

Rabeprazole specific:

- Hypersensitivity to derivatives of benzimidazoles.
- In pregnancy and during breast-feeding.

4.4 Special warnings and precautions for use

Amoxicillin

Before initiating therapy, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other beta-lactam agents. Serious and occasionally fatal hypersensitivity reactions have been reported on penicillin therapy, particularly in atopic individuals. If an allergic reaction occurs, amoxicillin must be discontinued and appropriate alternative therapy instituted.

Amoxicillin should be avoided if infectious mononucleosis is suspected, as morbilliform rash may occur. Prolonged use may occasionally result in overgrowth of non-susceptible organisms. Antibiotic-associated colitis (including pseudomembranous colitis) has been reported; if colitis develops, amoxicillin should be immediately discontinued and appropriate therapy initiated — anti-peristaltic medicinal products are contraindicated. Periodic assessment of organ system functions (renal, hepatic, haematopoietic) is advisable during prolonged therapy.

Prolongation of prothrombin time has been reported rarely. Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly.

Levofloxacin

Tendinitis and tendon rupture: Tendinitis may occur, most frequently involving the Achilles tendon. The risk is increased in patients >60 years, in patients on corticosteroids and in those receiving daily doses of 1000 mg. If tendinitis is suspected, treatment must be halted immediately and appropriate treatment (e.g. immobilisation) initiated. Tendon rupture may occur during or up to several months after stopping treatment.

Clostridium difficile-associated disease: Diarrhoea, particularly if severe, persistent and/or bloody, may be symptomatic of CDAD. If suspected or confirmed, levofloxacin should be stopped immediately; anti-peristaltic drugs are contraindicated.

QT interval prolongation: Levofloxacin should be used with caution in patients receiving drugs known to prolong the QT interval (class IA and III antiarrhythmics, tricyclic antidepressants, macrolides, antipsychotics).

Patients predisposed to seizures: Quinolones may lower the seizure threshold; levofloxacin is contraindicated in patients with epilepsy and should be used with extreme caution in patients predisposed to seizures or those on theophylline.

G-6-phosphate dehydrogenase deficiency: Risk of haemolytic reactions; monitor for possible occurrence of haemolysis.

Hypersensitivity reactions: Serious, potentially fatal reactions have been reported; discontinue immediately and initiate emergency measures.

Rabeprazole

Symptomatic response to rabeprazole does not exclude gastric or oesophageal malignancy. Patients on long-term treatment should be kept under regular surveillance. Caution when treatment is first initiated in patients with severe hepatic dysfunction. A risk of cross-hypersensitivity with other PPIs or substituted benzimidazoles cannot be excluded. Post-marketing reports of blood dyscrasias (thrombocytopenia and neutropenia) and hepatic enzyme abnormalities have been received.

Rabeprazole produces profound and long-lasting inhibition of gastric acid secretion. An interaction with compounds whose absorption is pH-dependent may occur (e.g. ketoconazole decreases by 30%, itraconazole increases by 22%). PPIs, including rabeprazole, should not be co-administered with atazanavir.

Sunset yellow content

The levofloxacin component contains sunset yellow (E110). Sunset yellow may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Amoxicillin interactions

Oral anticoagulants (warfarin, acenocoumarol):

If co-administration is necessary, prothrombin time or INR should be carefully monitored.

Methotrexate:

Penicillins may reduce the excretion of methotrexate, causing a potential increase in toxicity.

Probenecid (not recommended):

Decreases renal tubular secretion of amoxicillin, resulting in increased and prolonged blood levels.

Allopurinol:

Concomitant use may increase the likelihood of allergic skin reactions.

Levofloxacin interactions

Iron salts, zinc salts, magnesium/aluminium-containing antacids, didanosine:

Significantly reduce levofloxacin absorption. Do not take within 2 hours before or after levofloxacin administration.

Sucralfate:

Significantly reduces levofloxacin bioavailability. Administer sucralfate at least 2 hours after levofloxacin.

Theophylline and NSAIDs:

Pronounced lowering of the cerebral seizure threshold may occur when quinolones are given concurrently.

Vitamin K antagonists (warfarin):

Increased coagulation tests (PT/INR) and bleeding have been reported. Monitor coagulation tests.

Ciclosporin:

Half-life of ciclosporin was increased by 33%.

Probenecid and cimetidine:

Reduce renal clearance of levofloxacin (cimetidine by 24%, probenecid by 34%). Caution particularly in renally impaired patients.

Rabeprazole interactions

Rabeprazole is metabolised via CYP3A4 and CYP2C19. It does not interact in a clinically significant way with warfarin, phenytoin, theophylline or diazepam. Ketoconazole plasma levels decrease by 30% and itraconazole levels increase by 22% when co-administered with rabeprazole; individual patients may need monitoring. Atazanavir should not be co-administered with rabeprazole (see section 4.4).

4.6 Fertility, pregnancy and lactation

Amoxicillin:

Should be avoided during pregnancy unless considered essential by the physician. Limited human data do not indicate increased risk of congenital malformations. Amoxicillin is excreted in breast milk; diarrhoea and fungal infection of the mucous membranes are possible in the breast-fed infant. Use during breast-feeding only after benefit/risk assessment.

Levofloxacin:

Must not be used in pregnant women (see section 4.3). Contraindicated in breast-feeding women (see section 4.3).

Rabeprazole:

Contraindicated in pregnancy and during breast-feeding (see section 4.3). Reproduction studies in rats and rabbits revealed no evidence of impaired fertility or harm to the foetus, although foetal-placental transfer occurs in rats.

4.7 Effects on ability to drive and use machines

Amoxicillin: Undesirable effects (e.g. allergic reactions, dizziness, convulsions) may influence the ability to drive and use machines.

Levofloxacin: Dizziness/vertigo, drowsiness and visual disturbances may impair the patient's ability to concentrate and react.

Rabeprazole: Unlikely to cause impairment. If alertness is impaired due to somnolence, driving and operating complex machinery should be avoided.

4.8 Undesirable effects

Amoxicillin — selected adverse reactions

Very common: Diarrhoea. Common: Nausea, vomiting, mucocutaneous candidiasis. Uncommon: Dizziness, headache, indigestion, rises in AST/ALT, skin rash, pruritus, urticaria. Rare: Leucopenia, thrombocytopenia, erythema multiforme. Not known: Reversible agranulocytosis, haemolytic anaemia, prolongation of bleeding time, angioneurotic oedema, anaphylaxis, SJS, TEN, bullous exfoliative dermatitis, AGEP, antibiotic-associated colitis, hepatitis, cholestatic jaundice, interstitial nephritis.

Levofloxacin — selected adverse reactions

Common: Diarrhoea, nausea, vomiting, insomnia, headache, hepatic enzyme increased. Uncommon: Leukopenia, eosinophilia, anorexia, anxiety, confusion, dizziness, somnolence, abdominal pain, dyspepsia, constipation, flatulence, bilirubin increased, renal failure, rash, urticaria, pruritus, myalgia, arthralgia. Rare: Thrombocytopenia, neutropenia, hypoglycaemia, psychotic reactions, depression, hallucinations, peripheral neuropathy, seizure, tachycardia, hypersensitivity reactions. Not known: Pancytopenia, agranulocytosis, haemolytic anaemia, anaphylactic shock, tendon rupture, jaundice/severe liver injury, haemorrhagic diarrhoea/pseudomembranous colitis, CDAD.

Rabeprazole — selected adverse reactions

Common: Infections, insomnia, headache, dizziness, diarrhoea, vomiting, nausea, abdominal pain, constipation, flatulence, cough, pharyngitis, rhinitis, non-specific pain, back pain, asthenia, influenza-like illness. Uncommon: Nervousness, somnolence, bronchitis, sinusitis, dyspepsia, dry mouth, rash, erythema, myalgia, leg cramps, arthralgia, urinary tract infection, chest pain, increased hepatic enzymes. Rare: Neutropenia, leucopenia, thrombocytopenia, systemic allergic reactions, anorexia, depression, visual disturbance, gastritis, stomatitis, taste disturbance, hepatitis, jaundice, pruritus, bullous reactions, interstitial nephritis, weight increase. Very rare: Erythema multiforme, TEN, SJS. Not known: Hyponatraemia, confusion, peripheral oedema, gynaecomastia.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Amoxicillin: Gastrointestinal symptoms and fluid/electrolyte imbalance may be evident. Amoxicillin can be removed from the circulation by haemodialysis.

Levofloxacin: The most important signs to be expected include CNS symptoms (confusion, dizziness, impairment of consciousness, convulsions), QT interval prolongation and GI reactions (nausea, mucosal erosions). ECG monitoring should be undertaken. No specific antidote exists; haemodialysis is not effective.

Rabeprazole: Experience with overdose is limited. Effects are generally minimal and reversible. No specific antidote known. Rabeprazole is extensively protein bound and is not dialysable. Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC codes: Amoxicillin: J01CR02; Levofloxacin: J01MA12; Rabeprazole: A02BC04.

Amoxicillin is a semisynthetic penicillin (beta-lactam antibiotic) that inhibits penicillin-binding proteins (PBPs) in the biosynthetic pathway of bacterial peptidoglycan, resulting in cell lysis and death. Amoxicillin is susceptible to beta-lactamase-mediated degradation.

Levofloxacin is a fluoroquinolone antibacterial agent that acts on the DNA-gyrase complex and topoisomerase IV. Its bactericidal activity depends on the ratio of Cmax or AUC to the minimal inhibitory concentration (MIC).

Rabeprazole belongs to the class of substituted benzimidazoles (proton pump inhibitors) that suppress gastric acid secretion by specific inhibition of the H+/K+-ATPase enzyme. As a weak base, rabeprazole is rapidly absorbed and concentrated in the acid environment of parietal cells, where it is converted to the active sulphenamide form.

5.2 Pharmacokinetic properties

Amoxicillin: Rapidly and well absorbed orally; approximately 70% bioavailable. Tmax approximately 1 hour. About 18% bound to plasma proteins. Primarily eliminated renally. Crosses the placenta; detected in breast milk. The amoxicillin component is partly excreted as inactive penicilloic acid (up to 25% of dose).

Levofloxacin: Rapidly and almost completely absorbed orally; absolute bioavailability approximately 100%. Tmax approximately 1 hour. Approximately 30–40% bound to serum protein. Eliminated primarily by renal route (>85% of administered dose). Elimination half-life 6–8 hours.

Rabeprazole: Absorption begins after the tablet leaves the stomach (enteric-coated formulation). Peak plasma levels 3–5 hours after a 40 mg dose. Absolute bioavailability approximately 52%. Approximately 97% protein bound. Metabolised via CYP2C19 and CYP3A4. Approximately 90% eliminated in urine as the mercapturic acid conjugate (M5) and carboxylic acid (M6) metabolites. Plasma half-life approximately 1 hour.

5.3 Preclinical safety data

Amoxicillin: Non-clinical data reveal no special hazard for humans. Carcinogenicity studies have not been conducted.

Levofloxacin: Non-clinical data reveal no special hazard for humans. Levofloxacin caused chromosome aberrations in Chinese hamster lung cells in vitro (attributed to topoisomerase II inhibition); in vivo tests showed no genotoxic potential. Effects on cartilage (blistering and cavities) were observed in young rats and dogs — more marked in young animals.

Rabeprazole: Studies on mutagenicity gave equivocal results (positive in mouse lymphoma; negative in vivo micronucleus and DNA repair tests). Carcinogenicity studies revealed no special hazard for humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Amoxicillin 1000 mg:

Microcrystalline cellulose, PVP K-30, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, purified talc, isopropyl alcohol, methylene chloride, titanium dioxide, hydroxypropylmethylcellulose (HPMC).

Levofloxacin 500 mg:

Maize starch, microcrystalline cellulose, PVP K-30, purified water, purified talc, magnesium stearate, sodium starch glycolate, colloidal anhydrous silica, isopropyl alcohol, methylene chloride, Tween 80, PEG 6000, HPMC, titanium dioxide, Sunset Yellow Supra (excipient with known effect).

Rabeprazole 20 mg:

Mannitol, sodium bicarbonate, povidone K-30, isopropyl alcohol, purified talc, magnesium stearate, colloidal anhydrous silica, croscarmellose sodium, methylene dichloride, titanium dioxide, iron oxide red.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

6.5 Nature and contents of container

Each kit contains: 2 tablets of Amoxicillin 1000 mg packed in one ALU-ALU blister; 2 tablets of Levofloxacin 500 mg packed in one ALU-ALU blister; 2 tablets of Rabeprazole 20 mg packed in one ALU-ALU blister. One kit provides the morning and evening doses for one day. The pack contains 7 such kits.

6.6 Special precautions for disposal and other handling

No special handling requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

NATIONAL PHARMACY LIMITED
Colchester Park, P.O. Box 17843-00500, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2026/CTD10837/23368

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

17.12.2025

10. DATE OF REVISION OF THE TEXT

17.12.2025