SUMMARY OF PRODUCT CHARACTERISTICS

HELICOS KIT (Gastro-resistant Lansoprazole Capsules BP 30 mg / Amoxicillin Tablets BP 1 g / Clarithromycin Tablets USP 500 mg — Combipack)

1. NAME OF THE MEDICINAL PRODUCT

HELICOS KIT

(Combipack of Gastro-resistant Lansoprazole Capsules BP 30 mg, Amoxicillin Tablets BP 1 g and Clarithromycin Tablets USP 500 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lansoprazole Capsules BP 30 mg

Each gastro-resistant hard gelatine capsule contains lansoprazole BP 30 mg (as enteric-coated pellets).

Capsule shell: Peach cap / Pink body, hard gelatin size '2' (containing white to off-white enteric-coated pellets).

Amoxicillin Tablets BP 1 g

Each film-coated tablet contains amoxicillin trihydrate BP equivalent to amoxicillin 1 g.

Colour: Sunset Yellow FCF (E110).

Tablet: Orange coloured, caplet-shaped, biconvex, film-coated tablet with a break-line on one side.

Clarithromycin Tablets USP 500 mg

Each film-coated tablet contains clarithromycin USP 500 mg.

Colour: Titanium dioxide (E171).

Tablet: White, capsule-shaped, film-coated tablet, plain on both sides.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Combipack of: gastro-resistant capsules, film-coated tablets and film-coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

HELICOS KIT is indicated for the eradication of Helicobacter pylori (H. pylori) in adults with H. pylori-associated peptic ulcer disease (duodenal or gastric ulcer), as part of standard triple therapy.

Successful H. pylori eradication reduces the risk of duodenal and gastric ulcer recurrence. Consideration should be given to official guidance on the appropriate use of antibacterial agents and to the prevalence of local antimicrobial resistance.

4.2 Posology and method of administration

Adults

HELICOS KIT is administered twice daily (morning and evening) for 7, 10 or 14 days as directed by the physician, in accordance with local H. pylori eradication protocols.

Each dose (morning and evening) consists of:

- Lansoprazole 30 mg: 1 capsule taken at least 30 minutes before food.
- Amoxicillin 1 g: 1 tablet, with or without food.
- Clarithromycin 500 mg: 1 tablet, with or without food.

Lansoprazole should be taken at least 30 minutes before food for optimal efficacy. Amoxicillin and clarithromycin tablets may be given irrespective of food intake. Lansoprazole capsules should be swallowed whole with liquid; the capsule should not be chewed or crushed.

Renal impairment

Lansoprazole: No dose adjustment required. Amoxicillin: Dose reduction required in severe impairment (GFR 10–30 ml/min: maximum 500 mg twice daily; GFR <10 ml/min: maximum 500 mg once daily). Clarithromycin:

In patients with CrCl <30 ml/min, reduce the dose by one-half (250 mg once daily, or 250 mg twice daily in severe infections); treatment should not exceed 14 days. This fixed-dose combination may not be appropriate in severe renal impairment — individual component dosing is preferred.

Hepatic impairment

Lansoprazole: Use with caution in moderate to severe hepatic impairment; exposure is doubled in mild impairment and much more increased with moderate/severe impairment. Amoxicillin: Dose with caution; monitor hepatic function regularly. Clarithromycin: Contraindicated in patients with severe hepatic failure combined with renal impairment. Use with caution in patients with hepatic impairment.

Elderly

No dose adjustment required. Elderly patients are more likely to have decreased renal function; monitor renal function.

Paediatric population

The safety and efficacy of HELICOS KIT for H. pylori eradication in children and adolescents under 18 years have not been established. This combination is not recommended in this age group.

Method of administration

Oral. All three components are taken orally twice daily.

4.3 Contraindications

- Hypersensitivity to lansoprazole, substituted benzimidazoles or to any of the excipients listed in section 6.1.
- Hypersensitivity to amoxicillin, any other penicillin, or to any of the excipients listed in section 6.1. History of severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam agent (cephalosporin, carbapenem or monobactam). History of jaundice/hepatic impairment due to amoxicillin.
- Hypersensitivity to clarithromycin, other macrolides or to any of the excipients listed in section 6.1.
- Concomitant use of lansoprazole with atazanavir.
- Concomitant use of clarithromycin with: astemizole, cisapride, pimozide, terfenadine, ticagrelor, ranolazine (risk of QT prolongation and fatal arrhythmias); ergotamine or dihydroergotamine (risk of ergot toxicity); HMG-CoA reductase inhibitors extensively metabolised by CYP3A4 (lovastatin or simvastatin — risk of myopathy/rhabdomyolysis); colchicine; hypokalaemia (risk of QT prolongation).
- Clarithromycin in patients with history of QT prolongation or ventricular cardiac arrhythmia including torsades de pointes; severe hepatic failure combined with renal impairment.

4.4 Special warnings and precautions for use

Lansoprazole

Gastric malignancy: The possibility of malignant gastric disease should be excluded before treating a gastric ulcer with lansoprazole, as lansoprazole can mask symptoms and delay diagnosis.

Hypomagnesaemia: Severe hypomagnesaemia has been reported in patients treated with PPIs for at least 3 months (most cases after 1 year). Manifestations may include fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia. For patients expected to be on prolonged treatment or taking PPIs with digoxin or drugs that may cause hypomagnesaemia (e.g. diuretics), magnesium levels should be monitored before starting and periodically during treatment.

Bone fractures: PPIs — especially in high doses and over long duration (>1 year) — may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly.

Subacute cutaneous lupus erythematosus (SCLE): PPIs are associated with very infrequent cases of SCLE. If lesions occur in sun-exposed areas and are accompanied by arthralgia, the patient should seek medical help and lansoprazole should be discontinued.

Chromogranin A (CgA) interference: Increased CgA levels may interfere with investigations for neuroendocrine tumours. Lansoprazole should be stopped for at least 5 days before CgA measurements.

GI infections: Decreased gastric acidity may slightly increase the risk of Salmonella and Campylobacter gastrointestinal infections.

Colitis: Very rare cases have been reported; if severe or persistent diarrhoea occurs, discontinuation of therapy should be considered.

Amoxicillin

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

C. difficile-associated diarrhoea (CDAD): Antibiotic-associated colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening. CDAD must be considered in all patients presenting with diarrhoea following antibiotic use, including up to 2 months after administration.

Infectious mononucleosis: Amoxicillin should be avoided if infectious mononucleosis is suspected, as morbilliform rash has been associated with amoxicillin use in this condition.

Convulsions: May occur in patients with impaired renal function or in those receiving high doses.

Crystalluria: At high doses, adequate fluid intake and urinary output should be maintained to reduce the possibility of amoxicillin crystalluria.

Laboratory test interference: Amoxicillin may cause false positive urine glucose results with chemical test methods; enzymatic glucose oxidase methods should be used.

Clarithromycin

QT prolongation: Prolonged cardiac repolarisation and QT interval, imparting a risk of developing cardiac arrhythmia and torsade de pointes, have been reported with macrolides including clarithromycin. Clarithromycin should be used with particular caution in patients with coronary artery disease, severe cardiac insufficiency, conduction disturbances, clinically relevant bradycardia, electrolyte disturbances (especially hypokalaemia or hypomagnesaemia) or those taking other QT-prolonging medicinal products.

Hepatic failure: Fatal hepatic failure has been reported. Patients should be advised to stop treatment and contact their doctor if signs and symptoms of hepatic disease develop (anorexia, jaundice, dark urine, pruritus, tender abdomen).

CDAD: Pseudomembranous colitis and C. difficile-associated diarrhoea have been reported with clarithromycin and may range from mild to life-threatening.

Colchicine toxicity: Post-marketing reports of colchicine toxicity have been received. Deaths have been reported, especially in the elderly and those with renal insufficiency.

Statins: Concomitant use with lovastatin or simvastatin is contraindicated. Use of other statins with clarithromycin should be with caution; monitor for myopathy.

Resistance: Antibiotic resistance to clarithromycin among H. pylori strains is increasing. Where possible, susceptibility testing should guide therapy. If first-line eradication fails, susceptibility testing or alternative regimens should be considered.

4.5 Interaction with other medicinal products and other forms of interaction

Lansoprazole interactions

Atazanavir (contraindicated):

Co-administration results in approximately 90% reduction in atazanavir exposure.

Ketoconazole / itraconazole:

Lansoprazole may reduce their absorption; the combination should be avoided.

Digoxin:

Lansoprazole may increase digoxin plasma levels; monitor and adjust dose if necessary.

CYP3A4 substrates (tacrolimus, theophylline):

Lansoprazole may increase plasma concentrations of tacrolimus (by up to 81% increased exposure); monitor levels. Lansoprazole reduces theophylline concentrations; caution required.

CYP2C19 inhibitors (fluvoxamine):

May increase lansoprazole plasma concentrations up to 4-fold; dose reduction may be considered.

CYP2C19/CYP3A4 inducers (rifampicin, St. John's Wort):

May markedly reduce lansoprazole plasma concentrations.

Sucralfate/antacids:

May decrease lansoprazole bioavailability; take lansoprazole at least 1 hour after sucralfate or antacids.

Amoxicillin interactions

Probenecid (not recommended):

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

Allopurinol:

Concurrent administration increases the likelihood of allergic skin reactions.

Tetracyclines and other bacteriostatic drugs:

May interfere with the bactericidal effects of amoxicillin.

Oral anticoagulants (warfarin):

Cases of increased INR have been reported. PT/INR should be monitored when amoxicillin is added or withdrawn.

Methotrexate:

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

Clarithromycin interactions

Contraindicated combinations:

Cisapride, pimozide, astemizole, terfenadine (QT prolongation/arrhythmias), ergotamine/dihydroergotamine (ergot toxicity), lovastatin/simvastatin (myopathy/rhabdomyolysis), colchicine (toxicity/death), ticagrelor, ranolazine.

Warfarin and other oral anticoagulants:

Clarithromycin significantly increases INR and risk of serious haemorrhage; monitor INR/PT frequently.

Digoxin:

Clarithromycin inhibits P-glycoprotein, increasing digoxin exposure; monitor serum digoxin concentrations.

Oral hypoglycaemic agents/insulin:

Risk of significant hypoglycaemia; careful monitoring of glucose is recommended.

CYP3A4 substrates (carbamazepine, ciclosporin, tacrolimus, sildenafil, midazolam, triazolam, alprazolam, quinidine, disopyramide, rifabutin, vinblastine):

Clarithromycin inhibits CYP3A4; plasma concentrations of these drugs may be significantly increased. Monitor closely and reduce doses as necessary.

Calcium channel blockers metabolised by CYP3A4 (verapamil, amlodipine, diltiazem):

Caution — risk of hypotension.

CYP3A4 inducers (rifampicin, phenytoin, carbamazepine, phenobarbital, St. John's Wort):

May result in sub-therapeutic clarithromycin levels and reduced efficacy.

Fluconazole (in this combipack context):

Co-administration of fluconazole 200 mg with clarithromycin 500 mg twice daily increases clarithromycin Cmin and AUC by 33% and 18%, respectively; no dose adjustment is necessary. Note: HELICOS KIT does not contain fluconazole.

Zidovudine:

Simultaneous oral administration may result in decreased steady-state zidovudine concentrations; stagger doses by at least 4 hours.

4.6 Fertility, pregnancy and lactation

Pregnancy

Lansoprazole: Not recommended during pregnancy (no clinical data on exposed pregnancies). Amoxicillin: Limited data do not indicate an increased risk of congenital malformations; may be used in pregnancy when clearly necessary. Clarithromycin: Should not be used during pregnancy, particularly the first trimester, unless the potential benefits justify the risk; data from animal studies indicate embryotoxicity. This combination is not recommended during pregnancy — individual prescribing decisions should be made if antibiotic therapy is required.

Breast-feeding

Lansoprazole: Not known whether excreted in human breast milk; excreted in animal milk. The benefit/risk ratio should be considered. Amoxicillin: Excreted in breast milk in small quantities; the breast-fed infant may experience sensitisation, diarrhoea or fungal infection of mucous membranes. Clarithromycin: Excreted in human breast milk. Given the potential adverse effects on the breast-fed infant from all three components, HELICOS KIT should not be used during breast-feeding.

Fertility

No data on the effects of this combination on human fertility.

4.7 Effects on ability to drive and use machines

Adverse drug reactions such as dizziness, vertigo, confusion, somnolence and visual disturbances may occur with lansoprazole and clarithromycin. Amoxicillin may cause dizziness. Under these conditions the ability to react may be decreased.

4.8 Undesirable effects

Summary of the safety profile
The adverse reaction profile of HELICOS KIT reflects the combined profiles of lansoprazole, amoxicillin and clarithromycin. Common adverse reactions include gastrointestinal symptoms (nausea, vomiting, diarrhoea, abdominal pain), taste disturbances and headache.

System Organ Class	Common	Uncommon / Rare / Very rare
Infections	Oral/vaginal candidiasis (superinfection)	Pseudomembranous colitis, CDAD (rare–very rare)
Blood/lymphatic		Reversible leucopenia, thrombocytopenia, haemolytic anaemia, eosinophilia (all very rare)
Immune system		Severe hypersensitivity/anaphylaxis (very rare); urticaria, angioedema
Nervous system	Headache, dizziness	Paraesthesia, confusion, convulsions (very rare); vertigo, somnolence
Cardiac		QT prolongation, torsades de pointes (clarithromycin, rare)
Gastrointestinal	Nausea, vomiting, diarrhoea, abdominal pain, dyspepsia, flatulence, constipation	Antibiotic-associated colitis (rare); black hairy tongue (very rare); tooth discolouration (amoxicillin, children); metallic taste (clarithromycin)
Hepatobiliary	Elevated liver enzymes	Hepatitis, cholestatic jaundice, hepatic necrosis/failure (rare); jaundice (lansoprazole, very rare)
Skin	Rash, pruritus	SJS, TEN, AGEP, erythema multiforme (very rare); photosensitivity (lansoprazole)
Musculoskeletal		Myopathy/rhabdomyolysis (clarithromycin + statins interaction — rare)
Renal		Interstitial nephritis (lansoprazole); crystalluria (amoxicillin, very rare)
General/investigations		Hypomagnesaemia (lansoprazole, prolonged use); bone fractures (PPI, prolonged high-dose use)

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

Lansoprazole
Daily doses up to 180 mg orally and 90 mg IV have been administered in trials without significant undesirable effects. Acute toxicity is likely to be low. Gastric emptying, charcoal and symptomatic therapy are recommended if necessary. Lansoprazole is not significantly eliminated by haemodialysis.

Amoxicillin
Gastrointestinal symptoms (nausea, vomiting, diarrhoea) and disturbance of fluid and electrolyte balance may occur. Amoxicillin crystalluria may lead to renal failure. Convulsions may occur at high doses. Treat symptomatically. Amoxicillin may be removed from the circulation by haemodialysis.

Clarithromycin
Large amounts can produce gastrointestinal symptoms. Altered mental status, paranoid behaviour, hypokalaemia and hypoxaemia have been reported after ingestion of 8 g clarithromycin. Treat by prompt elimination of unabsorbed drug and supportive measures. Clarithromycin serum levels are not appreciably affected by haemodialysis or peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC codes: Lansoprazole: A02BC03; Amoxicillin: J01CA04; Clarithromycin: J01FA09.

Lansoprazole:

A proton pump inhibitor. Inhibits the final stage of gastric acid formation by irreversibly inhibiting the activity of H^+/K^+-ATPase of the gastric parietal cell. The inhibition is dose-dependent and reversible (through new enzyme synthesis). A single oral dose of 30 mg reduces basal secretion by approximately 70%; after 8 days of repeated administration, the reduction is approximately 85%. Lansoprazole creates an environment of reduced gastric acidity in which antibiotics are more effective against H. pylori.

Amoxicillin:

A semisynthetic penicillin (aminopenicillin). Inhibits one or more penicillin-binding proteins (PBPs) in the biosynthetic pathway of bacterial peptidoglycan, leading to cell wall weakening and cell lysis. Active against H. pylori. Susceptible to degradation by beta-lactamases. Pharmacokinetic/pharmacodynamic relationship: time above the MIC (T>MIC) is the major determinant of efficacy.

Clarithromycin:

A semi-synthetic macrolide antibiotic (6-O-methylerythromycin A). Exerts bacteriostatic (and at high concentrations bactericidal) action by binding to the 50S ribosomal subunit of susceptible bacteria, suppressing protein synthesis. Active against H. pylori in combination with a PPI. The 14-hydroxy metabolite also has antimicrobial activity.

5.2 Pharmacokinetic properties

Lansoprazole

Oral bioavailability 80–90% (single dose); reduced by approximately 50% with food — take before food. Peak plasma levels within 1.5–2 hours. Plasma protein binding 97%. Extensive hepatic metabolism (CYP2C19 predominantly, also CYP3A4); elimination half-life 1–2 hours in healthy subjects. Approximately one-third excreted in urine, two-thirds in faeces. Exposure is markedly increased in moderate/severe hepatic impairment and in CYP2C19 poor metabolisers.

Amoxicillin

Oral bioavailability approximately 70%; Tmax approximately 1 hour; not influenced by food. Volume of distribution approximately 0.3–0.4 L/kg; approximately 18% protein-bound. Elimination half-life approximately 1 hour; renal excretion is the major route (60–70% excreted unchanged in urine within 6 hours). Haemodialysis can be used for elimination.

Clarithromycin

Oral bioavailability approximately 50% (first-pass metabolism); food does not significantly affect extent of absorption. Volume of distribution 200–400 L; approximately 70% protein-bound. Extensively metabolised in the liver (CYP3A4); pharmacokinetics are non-linear (saturation of hepatic metabolism at high doses). Elimination half-life 2–4 hours at 250 mg twice daily; 5 hours at 500 mg twice daily. Approximately 20–40% excreted as unchanged drug in urine; 10–15% as active 14-hydroxy metabolite. Dose reduction required in severe renal impairment.

5.3 Preclinical safety data

Lansoprazole:

In rat carcinogenicity studies, dose-related gastric ECL cell hyperplasia and carcinoids, intestinal metaplasia, Leydig cell hyperplasia and benign Leydig cell tumours were observed (related to hypergastrinaemia). In mouse studies, liver tumours and adenoma of rete testis were seen. Retinal atrophy was observed after 18 months in rats but not in monkeys, dogs or mice. No genotoxicity. No special hazard in conventional safety pharmacology studies.

Amoxicillin:

No special hazard for humans based on studies of safety pharmacology, repeated dose toxicity, genotoxicity and reproductive/developmental toxicity. Carcinogenicity studies have not been conducted.

Clarithromycin:

Organ toxicity found in dogs and monkeys was dose-dependent (liver, stomach, thymus, lymphoid tissues, kidneys) at doses clearly above therapeutic levels. No mutagenic effects in vitro or in vivo. Administration at doses 2× the clinical dose in rabbit (IV) and 10× the clinical dose in monkey (oral) resulted in increased spontaneous abortions (associated with maternal toxicity). No embryotoxicity or teratogenicity in rats; cardiovascular malformations at 150 mg/kg/day in rats; cleft palate at very high doses in mice. Not tested for carcinogenicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lansoprazole Capsules BP 30 mg

Enteric-coated pellets (core): Dummy pellets (size 14, 18) — IH. Capsule shell: Hard gelatine capsule size '2' (peach cap, pink body).

(Full excipient list for enteric-coated pellets to be confirmed from approved CTD dossier — applicant to supply.)

Amoxicillin Tablets BP 1 g

Povidone (BP), microcrystalline cellulose (BP), purified talc (BP), magnesium stearate (BP), croscarmellose sodium (BP), Insta coat ICS 1100 Orange (IH — film coat containing Sunset Yellow FCF), isopropyl alcohol (BP), dichloromethane (BP).

Clarithromycin Tablets USP 500 mg

Lactose (BP), maize starch (BP), povidone (BP), magnesium stearate (BP), croscarmellose sodium (BP), colloidal anhydrous silica (BP), purified talc (BP), Insta coat ICS 223 White (IH — film coat containing titanium dioxide (E171)), isopropyl alcohol (BP), dichloromethane (BP).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30°C. Keep out of the reach of children.

6.5 Nature and contents of container

HELICOS KIT: 1 carton containing 6 daily dose packs (1 × 6 packs). Each daily dose pack (for morning or evening) contains:

- 1 blister containing 2 Lansoprazole Capsules (ALU/PVC, 1×2 capsules per blister)
- 1 blister containing 2 Amoxicillin Tablets (ALU/PVC, 1×2 tablets per blister)
- 1 blister containing 2 Clarithromycin Tablets (ALU/PVC, 1×2 tablets per blister)

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER

VAPI CARE PHARMA PVT. LTD.

Plot No. 225/3, GIDC, Nr. Morarji Circle,

Vapi – 396195, Gujarat, India.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

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26.01.2026

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