SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
Amoxicillin Tablets USP 1000 mg, Levofloxacin Tablets USP 500 mg, Vonoprazan Tablets 20 mg (VONOGLAX KIT)

2. Qualitative and quantitative composition
Amoxicillin Tablets USP 1000 mg
Each film coated tablet contains:
Amoxicillin Trihydrate USP
Eq to Amoxicillin 1000 mg
Excipients Q.S.
Colour: Titanium Dioxide BP

Levofloxacin Tablets USP 500 mg
Each film coated tablet contains:
Levofloxacin Hemihydrate USP
Eq. to Levofloxacin 500 mg
Excipients Q.S.
Colour: Red oxide of Iron & Titanium Dioxide BP

Vonoprazan Tablets 20 mg
Each film coated tablet contains
Vonoprazan Fumarate
Eq. to Vonoprazan 20 mg
Excipients Q.S.
Colours: Ferric Oxide Red & Titanium Dioxide BP

Excipient(s) with known effect
For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Film-coated tablet

Amoxicillin Tablets: White elongated biconvex shaped having score on one side, plain on other side film coated tablet.
Levofloxacin Tablets: Red, elongated, biconvex, score on one side, plain on other side, film coated tablet.
Vonoprazan Tablets: Brick red colour, round, biconvex, plain on both sides, film coated tablet.

4. Clinical particulars
4.1 Therapeutic indications
VONOGLAX Kit is a combikit, containing vonoprazan, amoxicillin, and Levofloxacin indicated for the treatment of *Helicobacter pylori (H. pylori)* infection in adults.
To reduce the development of drug-resistant bacteria and maintain the effectiveness of VONOGLAX Kit and other antibacterial drugs, VONOGLAX Kit should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

4.2 Posology and method of administration
VONOGLAX Kit: Carton of 7 daily administration packs for morning and evening dosing, each containing the following three drug products:
Amoxicillin: Dosage: 1000 mg twice a day
Levofloxacin: Dosage: 500mg twice a day
Vonoprazan: Dosage: 20 mg twice a day

VONOGLAX Kit: The recommended dosage regimen is vonoprazan 20 mg plus amoxicillin 1,000 mg plus Levofloxacin 500 mg, each given twice daily (morning and evening, 12 hours apart), with or without food, for 14 days.

4.3 Contraindications

Known hypersensitivity to vonoprazan, amoxicillin or any other betalactams, Levofloxacin or any other quinolone antimicrobial or any component of **VONOGLAX** Kit.

• in patients with epilepsy,
• in patients with history of tendon disorders related to Fluoroquinolone administration,
• in children or growing adolescents,
• during pregnancy,
• in breast-feeding women
• Rilpivirine-containing products.

4.4 Special warnings and precautions for use

VONOGLAX Kit

Hypersensitivity Reactions: Serious and occasionally fatal reactions (e.g., anaphylaxis) have been reported with components of VONOGLAX Kit. If hypersensitivity reactions occur, discontinue **VONOGLAX** Kit and institute immediate therapy (e.g., anaphylaxis management).

Severe Cutaneous Adverse Reactions (SCAR): Discontinue VONOGLAX Kit at the first signs or symptoms of SCAR or other signs of hypersensitivity and consider further evaluation**.**

Clostridioides difficile-associated diarrhea (CDAD): Evaluate if diarrhea occurs with **VONOGLAX Kit.**

• In case of sudden abdominal, chest or back pain, patients should be advised to immediately consult a physician in an emergency department.
• Patients should be advised to seek immediate medical attention in case of acute dyspnoea, new onset of heart palpitations, or development of oedema of the abdomen or lower extremities.
• increased risk of aortic aneurysm and dissection, particularly in elderly patients, and of aortic and mitral valve regurgitation.

QT Prolongation: Avoid **VONOGLAX Kit** in patients with known QT prolongation or receiving drugs known to prolong the QT interval, ventricular arrhythmia (torsades de pointes), hypokalemia/hypomagnesemia, significant bradycardia, or taking Class IA or III antiarrhythmics.

4.5 Interaction with other medicinal products and other forms of interaction

VONOGLAX KIT has the potential for clinically important drug interactions, including interactions with drugs dependent on gastric pH for absorption, drugs that are substrates for certain CYP enzymes, and some diagnostic tests. Avoid concomitant use of **VONOGLAX KIT** with atazanavir or nelfinavir.

Amoxicillin:

• Allopurinol: decreases toxicity of amoxicillin. Use with caution and monitor. Allopurinol may increase potential for allergic or hypersensitivity reactions to amoxicillin.
• Methotrexate: Amoxicillin increases levels of methotrexate by decreasing renal clearance. Use with caution and monitor. Increased serum concentrations of methotrexate with concomitant hematologic and gastrointestinal toxicity have been observed with concurrent administration of high or low doses of methotrexate and penicillins.
• Anticoagulants: Amoxicillin increases effects of warfarin anticoagulants. Use with caution and monitor.

Levofloxacin:

• Amiodarone and Levofloxacin both increase QTc interval. Avoid or use alternate drug.
• Calcium salts: Levofloxacin decreases levels of the other by inhibition of GI absorption. Use with caution and monitor. Separate taking both by 2 hours.
• Iron salts: Iron decreases levels of Levofloxacin by inhibition of GI absorption. Avoid concomitant use of iron.

• Digoxin: Levofloxacin will increase the level or effect of digoxin by altering intestinal flora. Use with caution and monitor.
• Sitagliptin: Levofloxacin increases effects of sitagliptin by pharmacodynamic synergism. Use with caution and monitor. May result in hyper- or hypoglycemia.

Vonoprazan:
Interacts with many other medicines. In particular, make sure that you discuss if you are using any of the following before taking Vonoglax Kit.
• Certain antiretrovirals, including rilpivirine, atazanavir, or nelfinavir, which are used for HIV or AIDS. Vonoprazan reduces intragastric acidity, which may alter the absorption of antiretroviral drugs, leading to changes in the safety and/or effectiveness.
Concomitant use with **VONOGLAX KIT** is contraindicated.
• Clopidogrel - Vonoprazan may reduce plasma concentrations of the active metabolite of clopidogrel and may cause reduction in platelet inhibition. Carefully monitor the efficacy of clopidogrel and consider alternative anti-platelet therapy.
• Citalopram and cilostazol-Vonoprazan may increase exposure of CYP2C19 substrate drugs so carefully monitor patients for adverse reactions associated with cilostazol.Carefully monitor patients for adverse reactions associated with citalopram and cilostazol.
• Mycophenolate mofetil -Vonoprazan reduces intragastric acidity, which may decrease the absorption of drugs reducing its effectiveness., Use with caution and monitor. Enteric-coated mycophenolate sodium may be less sensitive to this interaction.
• Antifungal agents, including ketoconazole and itraconazole- Vonoprazan will decrease the level or effect of itraconazole by inhibition of GI absorption. Applies only to oral form of both agents. Modify therapy and monitor closely. Closely monitor for reduced itraconazole efficacy if combined. Itraconazole capsules only: Separate administration by at least 1 hour before or 2 hours after ketoconazole.
• Certain tyrosine kinase inhibitors, including dasatinib, erlotinib, or nilotinib, which are used to treat specific types of cancer.
Vonoprazan will decrease the level or effect of tyrosine kinase inhibitors by inhibition of GI absorption. Avoid or use alternate drug.

4.6 Fertility, pregnancy and lactation
Pregnancy*:*
There are limited amount of data from the use of Levofloxacin in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. However, in the absence of human data and due to the experimental risk of damage by Fluoroquinolones to the weight-bearing cartilage of the growing organism, **VONOGLAX KIT** must not be used in pregnant women.
Lactation:
Breastfeeding is not recommended during treatment. Because of the potential risk of adverse liver effects shown in animal studies with vonoprazan, advise patients not to breastfeed during treatment with **VONOGLAX KIT.**

4.7 Effects on ability to drive and use machines
No studies on the effects on the ability to drive and use machines have been performed. However, as this medicine may cause dizziness, patients should be warned to be cautious when driving or operating machinery.

4.8 Undesirable effects
VONOGLAX Kit**:** The most common adverse reactions (≥2% in any treatment arm) include dysgeusia (5%), diarrhea (4%), vulvovaginal candidiasis (3%), headache (3%), abdominal pain (2%), hypertension (2%), and nasopharyngitis (<1%).

Other adverse reactions occurring in <2% of patients with **VONOGLAX** Kit are listed below by body system:

Blood and lymphatic system disorders: anemia, leukocytosis, leukopenia, neutropenia.

Cardiac disorders: QT prolongation, tachycardia.

Eye disorders: orbital edema.

Gastrointestinal disorders: abdominal distension, constipation, dry mouth, duodenal polyp, duodenal ulcer, dyspepsia, flatulence, gastric ulcer, gastroesophageal reflux disease, hematochezia, large intestine polyp, nausea, rectal polyp, stomatitis, tongue discomfort, vomiting.

General disorders and administration site conditions: fatigue, pyrexia.

Immune system disorders: drug hypersensitivity,

Infections and infestations: anal fungal infection, gastrointestinal viral infection, oral fungal infection, pneumonia, tongue fungal infection, upper respiratory tract infection, urinary tract infection, viral infection.

Investigations: liver function test abnormal.

Metabolism and nutrition disorders: decreased appetite.

Musculoskeletal system: bone fracture.

Nervous system disorders: ageusia, dizziness, tension headache.

Psychiatric disorders: anxiety, depression, insomnia.

Renal and urinary disorders: renal hypertrophy, tubulointerstitial nephritis.

Reproductive system and breast disorders: vaginal discharge.

Respiratory, thoracic and mediastinal disorders: cough, nasal polyps, oropharyngeal pain.

Skin and subcutaneous tissue disorders: dermatitis, dry skin, rash.

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 requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose

Amoxicillin

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically with attention to the water/electrolyte balance. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed. Amoxicillin may be removed from the circulation by haemodialysis.

Levofloxacin

According to toxicity studies in animals or clinical pharmacology studies performed with supratherapeutic doses, the most important signs to be expected following acute overdosage of levofloxacin are central nervous system symptoms such as confusion, dizziness, impairment of consciousness, and convulsive seizures, increases in QT interval as well as gastro-intestinal reactions such as nausea and mucosal erosions. CNS effects including confusional state, convulsion, hallucination, and tremor have been observed in post marketing experience. In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation. Antacids may be used for protection of gastric mucosa. Haemodialysis, including peritoneal dialysis and CAPD, are not effective in removing levofloxacin from the body. No specific antidote exists.

Vonoprazan

There is no experience of overdose with vonoprazan.

Vonoprazan is not removed from the circulation by hemodialysis. If overdose occurs, treatment should be symptomatic and supportive.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacological Action:

I) Helicobacter pylori is a Gram-negative bacterium that inhibits various areas of the stomach and duodenum and causes a chronic inflammation of the stomach lining and may cause development of duodenal, gastric ulcers and stomach cancer.

ii) Treatment usually involves a combination of antibiotics and acid suppressors.

iii) Antibiotics are used to kill the bacteria which reduces the risk of treatment failure and antibiotic resistance

iv) Thus triple therapy with Amoxycillin and Levofloxacin is indeed highly effective for treatment of H. pylori infection.

v) Vonoprazan in combination with antibiotics was also recommended as a first-line and second-line treatment, especially in patients with evidence of antimicrobial-resistant infections.

MECHANISM OF ACTION

Amoxicillin is anantibacterial drug. This drug acts by inhibiting the synthesis of bacterial cell wall. It inhibits cross linkage between linear peptidoglycan polymer chains that make up a major component of the cell wall of both Gram positive and negative bacteria.

Levofloxacin is a synthetic antibacterial agent of the Fluoroquinolone class and is the S (-) enantiomer of the racemic drug substance ofloxacin. Levofloxacin acts on the DNA-DNA-gyrase complex and topoisomerase IV. It directly inhibits bacterial DNA synthesis.

Levofloxacin promotes the breakage of DNA strands by inhibiting DNA-gyrase in susceptible organisms, which inhibits the relaxation of supercoiled DNA.

Acid suppression enhances the replication of *H. pylori* bacteria and the stability and effectiveness of antimicrobials in the treatment of *H. pylori* infection.

Vonoprazan is a novel potassium-competitive acid blocker (P-CAB), produces a complete acid-inhibition effect with a rapid onset, sustaining pH at the targeted level (6–7) for over 24 h, and undergoing metabolism without CYP2C19 polymorphisms. It suppresses basal and stimulated gastric acid secretion at the secretory surface of thegastric parietal cell through inhibition of the H+, K+-ATPase enzyme system in a potassium competitive manner. Vonoprazan does not require activation by acid.

5.2 Pharmacokinetic properties

<u>Amoxicillin</u>

Absorption

Amoxicillin fully dissociates in aqueous solution at physiological pH. It is rapidly and well absorbed by the oral route of administration. Following oral administration, amoxicillin is approximately 70% bioavailable. The time to peak plasma concentration (T_{max}) is approximately one hour.

The pharmacokinetic results for a study, in which an amoxicillin dose of 250 mg three times daily was administered in the fasting state to groups of healthy volunteers are presented below.

C_{max}	**T_{max}***	**AUC $_{(0-24h)}$**	**T ½**
(µg/ml)	**(h)**	**(µg.h/ml)**	**(h)**
3.3 ± 1.12	1.5 (1.0-2.0)	26.7 ± 4.56	1.36 ± 0.56
*Median (range)			

In the range 250 to 3000 mg the bioavailability is linear in proportion to dose (measured as C_{max} and AUC). The absorption is not influenced by simultaneous food intake.

Haemodialysis can be used for elimination of amoxicillin.

Distribution

About 18% of total plasma amoxicillin is bound to protein and the apparent volume of distribution is around 0.3 to 0.4 l/kg.

Following intravenous administration, amoxicillin has been found in gall bladder, abdominal tissue, skin, fat, muscle tissues, synovial and peritoneal fluids, bile and pus. Amoxicillin does not adequately distribute into the cerebrospinal fluid.
From animal studies there is no evidence for significant tissue retention of drug-derived material. Amoxicillin, like most penicillins, can be detected in breast milk.
Amoxicillin has been shown to cross the placental barrier.

Biotransformation

Amoxicillin is partly excreted in the urine as the inactive penicilloic acid in quantities equivalent to up to 10 to 25% of the initial dose.

Elimination

The major route of elimination for amoxicillin is via the kidney.
Amoxicillin has a mean elimination half-life of approximately one hour and a mean total clearance of approximately 25 l/hour in healthy subjects. Approximately 60 to 70% of the amoxicillin is excreted unchanged in urine during the first 6 hours after administration of a single 250 mg or 500 mg dose of amoxicillin. Various studies have found the urinary excretion to be 50-85% for amoxicillin over a 24 hour period. Concomitant use of probenecid delays amoxicillin excretion.

Age

The elimination half-life of amoxicillin is similar for children aged around 3 months to 2 years and older children and adults. For very young children (including preterm newborns) in the first week of life the interval of administration should not exceed twice daily administration due to immaturity of the renal pathway of elimination. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Gender

Following oral administration of amoxicillin/ to healthy males and female subjects, gender has no significant impact on the pharmacokinetics of amoxicillin.

Renal impairment

The total serum clearance of amoxicillin decreases proportionately with decreasing renal function.

Hepatic impairment

Hepatically impaired patients should be dosed with caution and hepatic function monitored at regular intervals.

<u>Levofloxacin</u>

Absorption

Orally administered levofloxacin is rapidly and almost completely absorbed with peak plasma concentrations being obtained within 1- 2 h. The absolute bioavailability is 99- 100 %. Food has little effect on the absorption of levofloxacin. Steady state conditions are reached within 48 hours following a 500 mg once or twice daily dosage regimen.

Distribution

Approximately 30 - 40 % of levofloxacin is bound to serum protein. The mean volume of distribution of levofloxacin is approximately 100 l after single and repeated 500 mg doses, indicating widespread distribution into body tissues. Penetration into tissues and body fluids: Levofloxacin has been shown to penetrate into bronchial mucosa, epithelial lining fluid, alveolar macrophages, lung tissue, skin (blister fluid), prostatic tissue and urine. However, levofloxacin has poor penetration intro cerebro-spinal fluid.

Biotransformation

Levofloxacin is metabolised to a very small extent, the metabolites being desmethyl-levofloxacin and levofloxacin N-oxide. These metabolites account for < 5 % of the dose excreted in urine. Levofloxacin is stereochemically stable and does not undergo chiral inversion.

Elimination

Following oral and intravenous administration of levofloxacin, it is eliminated relatively slowly from the plasma ($t_{½}$: 6 - 8 h). Excretion is primarily by the renal route > 85 % of the administered dose). The mean

apparent total body clearance of levofloxacin following a 500 mg single dose was 175 +/-29.2 ml/min. There are no major differences in the pharmacokinetics of levofloxacin following intravenous and oral administration, suggesting that the oral and intravenous routes are interchangeable. Linearity Levofloxacin obeys linear pharmacokinetics over a range of 50 to 1000 mg.

Special Populations

Elderly subjects

There are no significant differences in levofloxacin kinetics between young and elderly subjects, except those associated with differences in creatinine clearance.

Gender differences

Separate analysis for male and female subjects showed small to marginal gender differences in levofloxacin pharmacokinetics. There is no evidence that these gender differences are of clinical relevance.

Vonoprazan

Vonoprazan does not exhibit time-dependent pharmacokinetics.

Absorption:

Absolute bioavailability has not been determined. Distribution: The mean binding rate is 85.2 to 88.0% when vonoprazan in the range of 0.1 to 10μg/mL is added to human plasma (in vitro).

Metabolism:

Vonoprazan is metabolized mainly by hepatic drug-metabolizing enzyme CYP3A4 and partially by CYP2B6, CYP2C19 and CYP2D6. Vonoprazan is also metabolized by sulfotransferase SULT2A.

Excretion and Elimination:

Excretion and elimination are through urine and faeces. Age, Gender, Race: Vonoprazan has not been studied in patients under 18 years of age. There are no clinically relevant gender effects of vonoprazan.

5.3 Preclinical safety data

Amoxicillin

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction and development.
Carcinogenicity studies have not been conducted with amoxicillin.

Levofloxacin

Non-clinical data reveal no special hazard for humans based on conventional studies of single dose toxicity, repeated dose toxicity, carcinogenic potential and toxicity to reproduction and development. Levofloxacin caused no impairment of fertility or reproductive performance in rats and its only effect on fetuses was delayed maturation as a result of maternal toxicity. Levofloxacin did not induce gene mutations in bacterial or mammalian cells but did induce chromosome aberrations in Chinese hamster lung cells in vitro. These effects can be attributed to inhibition of topoisomerase II. In vivo tests (micronucleus, sister chromatid exchange, unscheduled DNA synthesis, dominant lethal tests) did not show any genotoxic potential. Studies in the mouse showed levofloxacin to have phototoxic activity only at very high doses. Levofloxacin did not show any genotoxic potential in a photomutagenicity assay, and it reduced tumour development in a photocarcinogenity study. In common with other fluoroquinolones, levofloxacin showed effects on cartilage (blistering and cavities) in rats and dogs. These findings were more marked in young animals.

Vonoprazan

Carcinogenesis

Vonoprazan was non-carcinogenic in a long term carcinogenicity study in mice when administered the drug daily via oral gavage for up to 2 years at 6, 20, 60, and 200 mg/kg/day. Treatment-related tumors, related to exaggerated pharmacology or sepsis-specificity, were noted in the stomach and liver. In the stomach, benign and malignant neuroendocrine cell tumors were observed at ≥20 (males) and ≥60 (females) mg/kg/day and ≥6 (males) and ≥60 (females) mg/kg/day, respectively. In the liver, increased incidences of hepatocellular adenoma and carcinoma were observed at ≥20 (males) and ≥60 (females) mg/kg/day, and at ≥60 (males) and

200 (females) mg/kg/day, respectively. Hyperplasia of the neuroendocrine cells and associated tumors in the stomach may be due to hypergastrinemia as a consequence of inhibiting gastric acid secretion. The hepatocellular tumors are likely rodent-specific findings that are attributed to prolonged induction of hepatic drug-metabolizing enzymes. The NOAEL was <6 mg/kg/day.

Vonoprazan was non-carcinogenic in a long term carcinogenicity study in rats administered the drug via oral gavage at 5, 15, 50, and 150 mg/kg/day. Treatment-related tumors, related to exaggerated pharmacology or species-specificity, were noted in the stomach and liver. In the stomach, benign and malignant neuroendocrine cell tumors were observed at ≥5 mg/kg/day except for malignant neuroendocrine tumor at 50 mg/kg/day (males). In some instances, in benign and malignant neuroendocrine cell tumors, tumor cells showed eosinophilic change but these tumors were also judged to be of neuroendocrine cell origin. In the liver, increased incidences of hepatocellular adenoma and carcinoma were observed at ≥50 mg/kg/day except for hepatocellular carcinoma at 50 mg/kg/day (females). Tumor findings in the stomach and liver are believed to be due to hypergastrinemia as a consequence of inhibiting gastric acid secretion and rodent-specific induction of hepatic drug-metabolizing enzymes, respectively. The occurrence of 4 hepatocholangiocellular tumors at ≥50 mg/kg/day (males) were considered to be treatment-related because they were considered to be associated with induction of hepatocellular tumor, but pairwise comparison did not demonstrate a statistically significant effect.

Mutagenicity

Vonoprazan did not exhibit any mutagenic or clastogenic activity in the *in vitro* Ames assay, *in vitro* mammalian chromosome aberration assay, and *in vivo* rat micronucleus assay.

Impairment of Fertility

When administered daily via oral gavage to male and female rats, there were no effects on sperm analysis, estrous cycles or number of corpora lutea observed at doses up to 300 mg/kg/dose. Males were administered vonoprazan prior to and during mating and females dosed for 2 weeks pre-mating through Gestation Day (GD) 6. The NOAEL for male and female general toxicity was 30 mg/kg/day and ≥300 mg/kg/day for reproductive function and early embryonic development.

6. Pharmaceutical particulars

6.1 List of excipients

Amoxicillin Tablets

Magnesium Stearate, Purified Talc, Croscarmellose Sodium, Cross Povidone, Colloidal Anhydrous Silica, Microcrystalline Cellulose 112, Hypromellose (As E-15), Titanium Dioxide, Polyethylene Glycol (As 6000), Isopropyl Alcohol and Dichloromethane.

Levofloxacin Tablets

Microcrystalline Cellulose, Sodium Starch Glycolate, Cross carmellose Sodium, Sodium Lauryl Sulphate, Maize Starch, Sodium Benzoate, CrosPovidone, Povidone (As k-30), Polacrilin Potassium (Kyron T-314), Colloidal Anhydrous Silica, Magnesium Stearate, Lactose, Mannitol, Purified Talc, Purified Water, Hypromellose (As E-15), Titanium Dioxide, Polyethylene Glycol (As 6000), Isopropyl Alcohol, Dichloromethane and Colour Red oxide of Iron.

Vonoprazan Tablets

Mannitol, Microcrystalline cellulose-102, Fumaric Acid, Hydroxy Propyl Cellulose, Sodium Lauryl Sulphate, Purified Talc & Magnesium Stearate, Hypromellose (E-15), Titanium Dioxide, Polyethylene Glycol (As 6000), Col. Ferric Oxide Red, Iso Propyl Alcohol and Dichloromethane.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage
This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container
7 x 1 Alu-Alu Kits

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing authorisation holder
Galaxy Pharmaceutical Ltd.
PO Box 39107-00623, Nairobi, Kenya.

Manufacturer
Saitech Medicare Pvt. Ltd.
Trilokpur road, Kala-Amb
Dist. Sirmor, Himachal Pradesh (INDIA).

8. Marketing Authorization Number
CTD13387

9. Date of first <Registration> / Renewal of the <Registration>
15/07/2026

10. Date of revision of the text
15/07/2026