1.6.1 Summary of Product Characteristics(SPC)

1. NAME OF THE MEDICINAL PRODUCT

KLAVMOX LB 1000 (Amoxicillin & Clavulanate Potassium Tablets with Lactic Acid Bacillus)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each film coated tablet contains:

Amoxicillin Trihydrate

Equivalent to Amoxicillin USP.....875 mg

Clavulanate Potassium USP

Equivalent to Clavulanic Acid.....125 mg

Lactic Acid Bacillus 60 million spores

(Appropriate overages of Lactic Acid Bacillus Spores added)

Colour : Titanium Dioxide

Ingredient	**Spec.**	**Qty /Tablet (mg)**	**Overages**	**Qty/Tab with overages(mg)**
Amoxicillin Trihydrate (compacted) Eq. To Amoxicillin	USP	1004.40	4.54%	1050.00
Potassium Clavulanate diluted with Microcrystalline Cellulose or Avicel (1:1) equivalent to Clavulanic Acid 125 mg (Potency 41.0%)	USP	*125.00	20%	150.0 ≅ *365.854
Lactic Acid Bacillus Spores	--	10.00	--	20.0
Colloidal Silicon dioxide	USP	30.00	--	30.00
Sodium Starch Glycolate	USP	**34.146	--	**34.146
Magnesium Stearate	USP	15.00	--	15.00
Hydroxy Propyl methyl cellulose	USP	12.54	--	12.54
Ethyl Cellulose	USP	4.15	--	4.15
Titanium Dioxide	USP	27.45	--	27.45
Talcum	USP	18.43	--	18.43

Dibutyl Phthalate	USP	7.60	--	7.60
Isopropyl alcohol	USP	189.6	--	189.6
Methylene Chloride	USP	669.0	--	669.0

3. PHARMACEUTICAL FORM:

Tablets

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications:

The Amoxicillin / Clavulanic acid is indicated for the short-term treatment of bacterial infections when strains produce beta lactamases.

1. Upper respiratory tract infections
2. Lower respiratory tract infections
3. Urogenital infections
4. Gastro abdominal Infections
5. Infections of skin and soft tissue
6. Post-surgical infections

Lactic acid bacillus is effective for preventing diarrhoea caused by Amoxicillin and clavulanic acid.

4.2 Posology and Method of administration

The usual recommended daily dosage

Children over 2 years (25mg/kg/day)

2-6yrs (13-21kg):1-2 tablets Klavmox LB 375mg, 2 times a day

7-12yrs (22-40): 1 single compressed KLVAMOX LB 625mg 2times per day.

Adult: one Klavmox LB tablets 1000mg: 2 times per day

Adult (Severe infection) : 1 LB Klavmox tablets 1000 mg: each 8 hour.

Oral Administration: To minimize gastrointestinal intolerance, administer 30mins before of the meal.

4.3 Contraindications

The Amoxicillin / Clavulanic acid is against indicated in patients hypersensitive to any of the constituents.

4.4 Special warning and Precautions for use.

Caution should be exercised in patients with history of liver or kidney disease, elderly, and children.

Avoid long-term use of this medication; otherwise it may cause secondary infection.

4.5 Interactions with other medicinal products and other forms of interaction

The use of allopurinol during treatment may reduce the effectiveness of Amoxicillin cause allergic skin reactions. No study has been done against the use of allopurinol with amoxicillin + clavulanic acid.

4.6 Pregnancy and Lactation

Pregnancy: Klavmox LB should be used with caution in women in the first trimester of pregnancy.

Lactation

Amoxicillin has been shown to be excreted in human milk. Amoxicillin / clavulanate potassium use by nursing mothers may lead to sensitization of infants. Caution should be exercised when amoxicillin / clavulanate potassium is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

No data is available.

4.8 Undesirable effects

Gastrointestinal side effects such as nausea, vomiting, diarrhea, seem to be most popular with amoxicillin / clavulanic acid.

Approximately 3% of patients with adverse effects announce Amoxicillin / Clavulanic acid. Have noted a few cases of urticaria, anaphylaxis, behavioral changes and abnormal laboratory test. Of gastrointestinal adverse effects may be minimized by taking the medication with food.

4.9 Overdose

In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures as required. If the overdosage is very recent and there is no contraindication, an attempt at emesis or other means of removal of drug from the stomach may be performed. Interstitial nephritis resulting in oliguric renal failure has been reported in a small number of patients after overdosage with amoxicillin. Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of amoxicillin.

Problems of overdose with amoxicillin are unlikely to occur. If encountered, gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically with attention to the water/electrolyte balance. During administration of high doses of amoxicillin, adequate fluid intake and urinary output must be maintained to minimize the possibility of amoxicillin crystalluria. Amoxicillin can be removed from the circulation by hemodialysis.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Combinations of penicillins, incl. beta-lactamase inhibitors; ATC code: J01CR02.

Resistance to many antibiotics is caused by bacterial enzymes which destroy the antibiotic before it acts on the pathogen. Clavulanate acid in the amoxicillin / clavunate blocks lactamase enzyme responsible for the destruction of the antibiotic, thus rendering the organisms sensitive to the effect of rapid bactericidal voluntarily with amoxicillin concentrations in tissues.

Clinical trial amoxicillin / clavulanic acid proved clinically and bacteriologically superior to amoxicillin alone and at least as effective as other agents comparative, eg cephalosporins administered orally. The antibacterial activity of amoxicillin / clavulanic acid has been well established. Clavulanic Acid alone has only weak antibacterial activity except against Legionella sp. Some species of B. catarrhalis including Branharella Neisseria gonorrhoeae fragilis. The combination of amoxicillin with clavulanic acid suppresses the development of resistance in experimental conditions.

5.2 Pharmacokinetic properties

Clavulanic acid union with amoxicillin does not cause any appreciable change in the pharmacokinetics of either drug compared with their separate administration. After oral administration, the two components achieve peak plasma concentrations in about an hour and these concentrations show a direct relationship with the administered dose. The absolute bioavailability of clavulanic acid is about 60%. The absorption is unaffected by concomitant administration of event food, milk etc ... the clavulanic acid to a volume of distribution of approximately 25% of body weight is linked protein of about 22%. Both amoxicillin clavulanic acid that have a half-life of elimination of approximately 6 hours. They are primarily eliminated in the urine. Amoxicillin and clavulanic acid are bound to plasma proteins 30%. The half-life of amoxicillin and clavulanic acid after oral administration is approximately 1 hour 30 minutes.

Lactic acid-fast bacilli

These organisms are characterized by their Ability to produce lactic acid from the fermentation of sugar.

Bacteria from lactic acid are the most dominant clinical.

They are aerobic gram-positive and anaerobic organisms with optional terminal spores.

These organisms are expected to have several advantages. These spores have a long life and are the basis of good bowel health safeguarding gastric acidity.

Lactic acid-fast bacilli are added to amoxcilline and clavulanic acid because of their resistance to high temperatures and acidity of the medium. Good colonies proliferate in the intestine and produce lactic acid L (+). All this promotes the metabolism of the spleen compared to DL lactic acid or D (-) produced by most traditional antibiotics. These spores are able to germinate and develop in living organisms.

These lactic acid-fast bacilli are used to reduce the side effects of amoxicillin and clavulanic acid.

This combination protects the flora to prevent gastrointestinal disorders such as diarrhea, constipation, anorexia, mouth ulcers. This also promises good absorption of micronutrients and medications taken during the illness.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, genotoxicity and toxicity to reproduction.

Repeat dose toxicity studies performed in dogs with amoxicillin/clavulanic acid demonstrate gastric irritancy and vomiting, and discoloured tongue.

Carcinogenicity studies have not been conducted with amoxicillin/clavulanic acid or its components.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients

Colloidal silicon Dioxide

Sodium starch glycolate

Magnesium Stearate

Hydroxy propyl methyl cellulose

Ethyl cellulose

Isopropyl Alcohol

Methylene Chloride

Titanium Dioxide

Talcum

Dibutyl phthalate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months from the date of manufacture.

6.4 Special precautions for storage

Store below 25°C, protected from light & moisture.

6.5 Nature and contents of container

10 tablets packed in a printed Alu-Alu foil, such foil is packed in a monocarton. Along with leaflet and silica gel bag.

6.6 Instructions for use and handling

Keep out of reach of children.

7. MANUFACTURER

KILITCH DRUGS INDIA LTD

At: Plot No. D-16/7, T.T.C. Industrial area, M.I.D.C, Turbhe Navi Mumbai- 400703, Maharashtra, India.

8. MARKETING AUTHORISATION NUMBER(S) :

Not Applicable

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

Not Applicable

10. DATE OF REVISION OF THE TEXT:

Not Applicable

The Summary of Product Characteristics (SPC) is satisfactory.

11. DOSIMETRY (IF APPLICABLE):

Not Applicable

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE):

Not Applicable