

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **KLAVMOX LB 1000**

(Amoxicillin & Clavulanate Potassium Tablets with Lactic Acid Bacillus)

#### **Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

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## 1. Name of Product

Brand Name: KLAVMOX LB 1000

Generic Name: Amoxicillin & Clavulanate Potassium Tablets With Lactic Acid Bacillus

## 2. Description of Product

White, oblong, biconvex, film coated tablets having a break-line on one side.

## 3. What is in the medicine ?

### Composition :

Each film coated tablet contains:

Amoxicillin Trihydrate USP

Equivalent to Amoxicillin 875mg

Clavulanate Potassium USP

Equivalent to Clavulanic Acid 125mg

Lactic Acid Bacillus 60 million spores

(Appropriate overages of Lactic Acid Bacillus Spores added)

Colour : Titanium Dioxide

## 4. Strength of the Medicine

1000mg

## 5. What is this Medicine used for ?

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

## **6. How much and how often should you use this Medicine?**

### **How much is given**

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.

## **7. When should you not take this Medicine ?**

Caution in women in the first trimester of pregnancy.

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.

## **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.

### **9. What other medicine or food should be avoided whilst taking this medicine ?**

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.

### **10. What should you do if you miss a dose ?**

Use the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not use a double dose to make up for a missed one.

### **11. How should you keep this Medicine?**

Store below 25°C. Protect from light and moisture.

### **12. Sign & Symptoms of over dosage**

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.

### **13. What to do when you have taken more than the recommended dosage ?**

In case of overdosage, symptomatic therapy with attention to the water/electrolyte balance should be supported appropriately.

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.

#### **14. Care that should be taken when taking this Medicine ?**

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.

#### **15. When should you consult your doctor?**

Tell your doctor if you are taking other medicines that you buy without a prescription has from your pharmacy or health food shop. Some medicines may interfere with

##### **KLAVMOX LB.**

Tell your doctor if

- you are pregnant or intend to become pregnant
- breast-feeding or plan to breast-feed

#### **16. Name/logo of Marketing Authorization Holder**

**Manufactured and Marketed by :**



**KILITCH DRUGS (INDIA) LTD.**

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