

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

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## VIZYLAC

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### 1. Generic Name

Lactic Acid Bacillus Capsules.

### 2. Qualitative and quantitative composition

Each hard gelatin capsule contains:

Lactic acid Bacillus ...Not less than 120 million spores ( $120 \times 10^6$  spores)

Excipients: q.s.

Approved colour used in capsule shell.

The excipients used are Dibasic Calcium Phosphate Anhydrous, Maize Starch, Talc, Sodium Lauryl Sulphate and Magnesium Stearate.

### 3. Dosage form and strength

**Dosage form:** Capsules

**Strength:**  $120 \times 10^6$

### 4. Clinical particulars

#### 4.1 Therapeutic indication

For restoration of intestinal microflora.

#### 4.2 Posology and method of administration

One capsule once daily or as directed by physician.

#### 4.3 Contraindications

This medicine is not recommended for use in patients with a known allergy to lactic acid bacillus or any other inactive ingredients present along with it.

#### 4.4 Special warnings and precautions for use

##### Antibiotic therapy

If your doctor has prescribed this medicine along with antibiotics, then it should be taken between two scheduled doses of the antibiotics. Discuss therapy with your doctor to avoid/minimize the interaction between antibiotics and this medicine.

#### 4.5 Drugs interactions

**The common drug interactions have been noticed with the following drugs:**

- Alcohol (mild)
- Antibiotics (mild)
- Immunosuppressants (mild)

#### 4.6 Use in Special Populations (Such as Pregnant Women, Lactating Women, Paediatric Patients, Geriatric Patients Etc.) Pregnancy

This medicine is considered safe for use by a pregnant woman. However, Patients are

advised to consult your doctor before taking this medicine.

### **Breast-feeding**

This medicine is considered safe for use by a breastfeeding woman. However, Patients are advised to consult your doctor before taking this medicine.

### **4.7 Effects on ability to drive and use machines**

Not Available

### **4.8 Undesirable effects**

VIZYLAC is usually safe in populations like infants, adults, pregnant and lactating women but following side effects are seen in few cases:

Acute toxicity (less common)

Nausea (common)

Rashes (common)

Bloating (common)

Abdominal pain (less common)

### **4.9 Overdose**

Overdose may lead to increased chances of side effects.

## **5. Pharmacological properties**

### **5.1 Mechanism of Action**

The mechanism of action is presumed to be a result of improving gastrointestinal ecology made possible by replenishing the quantity of desirable obligate microorganisms and antagonizing pathogenic microbes.

### **5.2 Pharmacodynamic properties**

Despite the transient nature of this organism in the digestive tract, the changes that lactic acid bacillus produces cause a shift in the environment in support of a complex gastrointestinal flora.

Two isomeric forms of lactic acid can be produced by lactic acid-producing bacteria dextrorotatory (D (-)) lactic acid and laevorotatory (L (+)) lactic acid. L (+) lactic acid is completely metabolized in the body; however, D (-) lactic acid is not completely metabolized, resulting in a degree of metabolic acidosis. *Lactobacillus sporogenes* produces only L (+) lactic acid. *L. sporogenes* is assumed to produce bacteriocins and short-chain fatty acids. As the organism grows, it assimilates and incorporates cholesterol into its cellular structure. *L. sporogenes* possesses significant beta-galactosidase (lactase) activity *in vitro*.

### **5.3 Pharmacokinetic properties**

Subsequent to oral administration, VIZYLAC passes through the stomach in its spore form and upon arrival in the duodenum, germinates and multiplies rapidly. Estimates suggest that the average duration of time between oral dosing and germination is 4 hours. After germination, VIZYLAC metabolically active in the intestines, producing lactic acid. *L. sporogenesis* considered semi-resident, indicating that it takes up only a

temporary residence in the human intestines. Spores of VIZYLAC are excreted slowly via the faeces for approximately 7 days after discontinuation of administration.

## **6. Nonclinical properties**

### **6.1 Animal Toxicology or Pharmacology**

Not Available

## **7. Description**

Lactic Acid Bacillus Capsules are Pink/Pink hard gelatin Size 2 capsules containing white powder, printed with 'VIZYLAC' on both cap and body. The excipients used are Dibasic Calcium Phosphate Anhydrous, Maize Starch, Talc, Sodium Lauryl Sulphate and Magnesium Stearate.

## **8. Pharmaceutical particulars**

### **8.1 Incompatibilities**

Not applicable

### **8.2 Shelf-life**

Do not use later than the date of expiry

### **8.3 Packaging information**

VIZYLAC is available in strip of 15 Capsules.

### **8.4 Storage and handling instructions**

Store in a cool & dry place. Protect from light & moisture.

## **9. Patient Counselling Information**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### **What is in this leaflet?**

9.1. What Lactic VIZYLAC is and what it is used for

9.2. What you need to know before you use VIZYLAC

9.3. How to Take VIZYLAC

9.4. Possible side effects

9.5. How to store VIZYLAC

9.6. Contents of the pack and other information

### **9.1 What VIZYLAC is and what it is used for**

VIZYLAC contains Lactic Acid Bacillus. It is a probiotic used for restoration of intestinal microflora.

### **9.2 What you need to know before you use VIZYLAC**

This medicine is not recommended for use in patients with a known allergy to Lactic Acid Bacillus or any other inactive ingredients present along with it.

### **9.3 How to Take VIZYLAC**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Your doctor will tell you how to take the medicine each day and when to take them.
- Read the label on the carton to remind you what the doctor said.
- Try to take your capsule at the same time each day.

### **9.4 Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

VIZYLAC is usually safe in populations like infants, adults, pregnant and lactating women but following side effects are seen in few cases:

Acute toxicity (less common), Nausea (common), Rashes (common), Bloating (common), Abdominal pain (less common)

### **9.5 How to store VIZYLAC**

Store in a cool & dry place. Protect from light & moisture.

### **9.6 Contents of the pack and other information**

The active ingredient is Lactic acid bacillus

The excipients used are Dibasic Calcium Phosphate Anhydrous, Maize Starch, Talc, Sodium Lauryl Sulphate and Magnesium Stearate.

## **10. Details of manufacturer**

Uni Medicolabs

Plot No. 25 & 26, Pharmacity, Selaqui, Dehradun (Uttarakhand).

## **11. Details of permission or licence number with date**

Mfg Lic No. 31/UA/SC/P-2018 issued on 19.06.2018

## **12. Date of revision**

Not applicable

## **MARKETED BY**



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IN/VIZYLAC 120 x 10<sup>6</sup>/APR-20/01/PI