

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

VIZYLAC PLUS

1. Generic Name

Lactic Acid Bacillus Capsules.

2. Qualitative and quantitative composition

Each hard gelatin capsule (per serving) contains:

Lactic Acid Bacillus.....2.5 billion spores

(Bacillus Coagulans)

Other Ingredients: Starch, Sugar, Talc, Gelatin, Hydroxy Propyl Methyl cellulose, Polyvinyl Pyrrolidone, Methacrylic Acid Polymer, Sodium Methylparaben, Sodium Propyl Paraben and Tween 80.

Contains permitted synthetic food colours (Erythrosine, Sunset Yellow FCF & Titanium Dioxide)

Appropriate overages of Vitamins added to compensate for loss on storage.

3. Dosage form and strength

Dosage form: Capsules

Strength: 2.5 billion spores

4. Clinical particulars

4.1 Therapeutic indication

For restoration of intestinal microflora.

4.2 Posology and method of administration

Nutritional Information per serving (per capsule) (approx.)		
Energy	1.15	Kcal
Protein	0.02	g
Total Carbohydrate	0.268	g
Sugar	0.064	g
Starch	0.204	g

- Probiotic food
- Recommended Usage: As directed by the Healthcare Professional.
- Not for medicinal use

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 PLUS 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 PLUS 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 PLUS 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 PLUS 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 coloured, hard gelatin capsule size '2' filled with greyish & white coloured pellets. The other ingredients used are Starch, Sugar, Talc, Gelatin, Hydroxy Propyl Methyl cellulose, Polyvinyl Pyrrolidone, Methacrylic Acid Polymer, Sodium Methylparaben, Sodium Propyl Paraben, Tween 80 and CONTAINS PERMITTED SYNTHETIC FOOD COLOURS (Erythrosine, Sunset Yellow FCF & Titanium Dioxide).

8. Pharmaceutical particulars

8.1 Incompatibilities

Not applicable

8.2 Shelf-life

Best before 18 months from manufacture.

8.3 Packaging information

VIZYLAC PLUS is available in strip of 15 capsules.

8.4 Storage and handing instructions

Store below 25°C. Protect from light.

Keep out of reach of children.

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 PLUS is and what it is used for

9.2. What you need to know before you use VIZYLAC PLUS

9.3. How to Take VIZYLAC PLUS

9.4. Possible side effects

9.5. How to store VIZYLAC PLUS

9.6. Contents of the pack and other information

9.1 What VIZYLAC PLUS is and what it is used for

VIZYLAC PLUS 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 PLUS

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 PLUS

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 PLUS 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 PLUS

Store below 25°C. Protect from light.

9.6 Contents of the pack and other information

The active ingredient is Lactic acid bacillus

Other Ingredients: Starch, Sugar, Talc, Gelatin, Hydroxy Propyl Methyl cellulose, Polyvinyl Pyrrolidone, Methacrylic Acid Polymer, Sodium Methylparaben, Sodium Propyl Paraben and Tween 80.

Contains permitted synthetic food colours (Erythrosine, Sunset Yellow FCF & Titanium Dioxide)

Appropriate overages of Vitamins added to compensate for loss on storage.

10. Details of manufacturer

Ravenbhel Healthcare Pvt. Ltd.

16-17, EPIP, SIDCO, Kartholi, Bari-Brahmana, Jammu – 181133.

11. Details of permission or licence number with date

FSSAI Lic. No. 10014061000240

12. Date of revision

Not applicable

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