

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

VIZYLAC DRY POWDER

1. Generic Name

Lactic Acid Bacillus Powder.

2. Qualitative and quantitative composition

After reconstitution each 5ml contains:

Lactic acid Bacillus120 x 10⁶

Excipientsq.s.

Flavour: Pineapple

Appropriate overages added.

The excipients used are Sodium Chloride, Benzoic Acid, Saccharin Sodium, Sodium Lauryl Sulphate, Flavour Pineapple DC-106, Sucrose, Colloidal Silicon Dioxide and Magnesium Stearate.

3. Dosage form and strength

Dosage form: Dry powder

Strength: 120 x 10⁶

4. Clinical particulars

4.1 Therapeutic indication

For restoration of intestinal microflora.

4.2 Posology and method of administration

For Paediatric use

Dosage: 5ml (1 teaspoonful) twice a day for children above 1 year and 2.5ml (1/2 teaspoonful) once a day for infants below 1 year or as directed by the physician

Direction for use: Add boiled and cooled water upto the ring on the bottle and shake vigorously. Adjust the volume upto the ring by adding more water if necessary. This make 60ml syrup.

Consume within one week after reconstitution. Store reconstituted syrup below 25°C.

Shake well before 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. 4Special 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. 6Use 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. 7Effects on ability to drive and use machines

Not Available

4.8 Undesirable effects

VIZYLAC DRY POWDER 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 increase chances of side effects.

5. Pharmacological properties

5.1 Mechanism of Action

Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

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. 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. 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. *VIZYLAC DRY Powders* assumed to produce bacteriocins and short-chain fatty acids. As the organism grows, it assimilates and incorporates cholesterol into its cellular structure. *VIZYLAC DRY POWDER* possesses significant beta-galactosidase (lactase) activity *in vitro*.

5.3 Pharmacokinetic properties

Subsequent to oral administration, *VIZYLAC DRY POWDER* 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 DRY Powders* 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 DRY POWDER* 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

Vizylac Dry Powder is white coloured powder having pineapple odour, after reconstitution gives off white coloured turbid solution. The excipients used are Sodium Chloride, Benzoic Acid, Saccharin Sodium, Sodium Lauryl Sulphate, Flavour Pineapple DC-106, Sucrose, Colloidal Silicon Dioxide 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 DRY POWDER is available 60ml bottle

8.4 Storage and handing instructions

Store in a cool, dry place. Protect from light

Store reconstituted syrup below 25°C.

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 DP is and what it is used for
- 9.2. What you need to know before you use Vizylac DP
- 9.3. How to Take Vizylac DP
- 9.4. Possible side effects
- 9.5. How to store Vizylac DP
- 9.6. Contents of the pack and other information

9.1 What Vizylac DP is and what it is used for

Vizylac DP contains Lactic Acid Bacillus. It is a probiotic used to treat diarrhea caused due to infections, antibiotics, etc. It is also used to relieve symptoms of digestive disorders such as irritable bowel syndrome, inflammatory bowel disease, stomach ulcers, constipation, indigestion, etc.

9.2 What you need to know before you use Vizylac DP

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

9.3 How to Take Vizylac DP

Always take this medicine exactly as your doctor or pharmacist 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 tablet at the same time each day.

For Paediatric use

Appropriate overages added.

Dosage: 5ml (1 teaspoonful) twice a day for children above 1 year and 2.5ml (1/2 teaspoonful) once a day for infants below 1 year or as directed by the physician

Direction for use: Add boiled and cooled water up to the ring on the bottle and shake vigorously. Adjust the volume up to the ring by adding more water if necessary. This make 60ml syrup.

Consume within one week after reconstitution.

Shake well before use.

9.4 Possible side effects

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

VIZYLAC DRY Powder 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)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting. By reporting side effects, you can help provide more information on the safety of this medicine.

9.5 How to store Vizylac DP

Store in a cool, dry place. Protect from light

Store reconstituted syrup below 25°C.

9.6 Contents of the pack and other information

The active ingredient is Lactic acid bacillus

The excipients used are Sodium Chloride, Benzoic Acid, Saccharin Sodium, Sodium Lauryl Sulphate, Flavour Pineapple DC-106, Sucrose, Colloidal Silicon Dioxide and Magnesium Stearate.

10. Details of manufacturer

Manufactured in India by:

Uni Medicolabs

Plot No. 25-26, Pharmacy, Selaqui, Dehradun, Uttarakhand.

OR

Manufactured in India by:

Uni Medicolabs

At: NH-74, Roorkee-Dehradun Road, Kishanpur, Roorkee,

Dist.: Haridwar, Uttarakhand.

11. Details of permission or licence number with date

Mfg Lic No. 31/UA/SC/P-2018 issued on 19.06.1998.

OR

Mfg. Lic. No. 41/UA/LLSC/P-2018 issued on 07.08.1998.

12. Date of revision

Not available

MARKETED BY



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