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

Vizylac DT

1. Generic Name

Lactic Acid Bacillus and Zinc Sulphate Monohydrate Tablets.

2. Qualitative and quantitative Composition:

Each dispersible uncoated tablet contains:

Lactic Acid Bacillus ……. 120 x 10^6

Zinc Sulphate Monohydrate I.P.

(as Zinc Resinate)

Equivalent to elemental Zinc……10 mg

Excipients…..... q.s.

The excipients used are Microcrystalline Cellulose, Aerosil, Aspartame, Cross Carmellose Sodium, Cross Povidone, and Magnesium Stearate.

3. Dosage form and strength

Dosage form: Uncoated dispersible tablet

Strength: Lactic Acid Bacillus 120 x 10^6 and Zinc 10 mg

4. Clinical particulars

4.1. Therapeutic indication

It is indicated for the treatment of Diarrhea.

4.2. Posology and method of administration

Posology

As directed by the Physician.

Method of administration

Disperse the tablet in a teaspoonful of previously boiled and cooled water before administration.

4.3. Contraindications

- Hypersensitivity to Lactic Acid Bacillus and Zinc sulphate and other ingredients listed in prescribing information.
- Copper deficiency

4.4. Special warnings and precautions for use

Accumulation of zinc may occur in cases of renal failure.

This product contains sodium. This should be taken into consideration by patients on a controlled sodium diet.

Probiotics do not appear to pose any safety concerns for pregnant and lactating women. Systemic absorption is rare when probiotics are used by healthy individuals, and the current literature does not indicate an increase in adverse pregnancy outcomes.

4.5. Drugs interactions

Copper:

Zinc may inhibit the absorption of copper.

Tetracycline Antibacterial:

Zinc may reduce the absorption of concurrently administered tetracycline, also the absorption of zinc may be reduced by tetracycline; when both are being given an interval of at least three hours should be allowed.

Quinolone Antibacterial:

Zinc may reduce the absorption of quinolones; ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin.

Calcium Salts:

The absorption of zinc may be reduced by calcium salts.

Iron:

The absorption of zinc may be reduced by oral iron, also the absorption of oral iron may be reduced by zinc.

Penicillamine:

The absorption of zinc may be reduced by Penicillamine, also the absorption of penicillamine may be reduced by zinc.

Trientine:

The absorption of zinc may be reduced by trientine, also the absorption of trientine may be reduced by zinc.

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

The safety of this product in human pregnancy has not been established. Zinc crosses the placenta and is present in breast milk.

4.7. Effects on ability to drive and use machines

Vizylac DT has no influence on the ability to drive and use machines.

4.8. Undesirable effects

The following side effects may or may not occur due to the usage of this tablet. It is generally well tolerated when consumed in prescribed dosage guidelines. More common ones are generally mild and may include:

- Abdominal detention
- Bloating
- Skin rashes
- Loss of appetite
- Altered sleep patterns

Zinc salts may cause abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation and gastritis. There have also been cases of irritability, headache and lethargy observed.

Zinc may interfere with the absorption of copper, leading to reduced copper levels, and potentially copper deficiency. The risk of copper deficiency may be greater with longterm treatment (e.g. if zinc deficiency is no longer present) and/or with higher doses of zinc.

Reporting of adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Report suspected adverse reactions via any point of contact available at www.torrentpharma.com or at email: pv@torrentpharma.com or call on 1800-120-3001.

4.9. Overdose

Vizylac DT contains Zinc sulfate, it is corrosive in over dosage. Symptoms are corrosion and inflammation of the mucous membrane of the mouth and stomach; ulceration of the stomach followed by perforation may occur. Gastric lavage and emesis should be avoided. Demulcents such as milk should be given. Chelating agents such as sodium calcium edetate may be useful.

5. Pharmacological properties

5.1. Mechanism of Action

Zinc sulphate monohydrate

The physiological effect of zinc on intestinal ion transport has not yet been established thoroughly.

In a reported in-vitro study with rat ileum it is stated that zinc inhibits cAMP-induced, chloride-dependent fluid secretion by inhibiting basolateral potassium (K) channels. This study has also shown the specificity of Zn to cAMP-activated K channels, because zinc did not block the calcium (Ca)-mediated K channels. As this study was not performed in Zn-deficient animals, it provides evidence that Zn is probably effective in the absence of Zn deficiency. Zinc also improves the absorption of water and electrolytes, improves regeneration of the intestinal epithelium, increases the levels of brush border enzymes, and enhances the immune response, allowing for a better clearance of the pathogens Another report has recently provided evidence that zinc inhibits toxin-induced cholera, but not Escherichia coli heat-stable, enterotoxin-induced, ion secretion in cultured Caco-2 cells. Thus, Zinc plays an important role in modulating the host resistance to infectious agents and reduces the risk, severity, and duration of diarrheal diseases. It also plays a critical role in metallo-enzymes, polyribosomes, and the cell membrane and cellular function, giving credence to the belief that it plays a central role in cellular growth and in the function of the immune system.

Lactic acid bacillus

Modification of the gut microbiota, competitive adherence to the mucosa and epithelium, strengthening of the gut epithelial barrier and modulation of the immune system to convey an advantage to the host.

Lactobacillus is a friendly bacteria that normally stays in our digestive, genital and urinary system without causing any harm to our body. It helps to prevent types of diarrhea such as rotaviral diarrhea in children and traveler's diarrhea.

5.2. Pharmacodynamic properties

Zinc Sulphate Monohydrate

Zinc is an essential trace element involved in many enzyme systems. Severe deficiency causes skin lesion, alopecia, diarrhoea, increased susceptibility to infections and failure to thrive in children. Symptoms of less severe deficiency include distorted or absent perceptions of taste and smell and poor wound healing.

Lactic Acid Bacillus

Lactic acid produces a metabolic alkalinizing effect.

5.3. Pharmacokinetic properties

Zinc Sulphate Monohydrate

Zinc is absorbed from the gastrointestinal tract and distributed throughout the body. The highest concentrations occur in hair, eyes, male reproductive organs and bone. Lower levels are present in liver, kidney and muscle. In blood 80% is found in erythrocytes. Plasma zinc levels range from 70 to 110µg/dL and about 50% of this is loosely bound to albumin. About 7% is amino-acid bound and the rest is tightly bound to alpha 2- macroglobulins and other proteins.

Lactic Acid Bacillus

Adhesion to the intestinal epithelium. Many reported studies have shown that some probiotic strains can adhere to cell lines such as CaCo2 or HT29 these epithelial cell lines are of colonic or intestinal origin. The cells are polarized like in an intestinal epithelium, and many characteristics and functions of a normal epithelium are expressed on the cells. They are therefore thought to be fair models to predict in vivo adhesion. Using other cell lines or colon tissues have also been proposed. The epithelial adhesion property differs between strains, and this property might be correlated with competitive exclusion properties and immunomodulatory activities in vivo. Until now, competitive exclusion properties of adhering strains have only been shown in vitro. Validation of the in vitro models with in vivo data is therefore warranted, and the possibility for a probiotic to adhere to the intestinal epithelium during its intestinal transit has to be studied.

The capacities of survival of L. acidophilus acid conditions are higher than that of L. bulgaricus. About 1-10% of L. acidophilus ingested in fermented products were found to survive until the ileum in several human studies using intestinal intubation techniques In one of our studies, the concentrations of lactobacilli flowing through the ileum after ingestion of a cup of milk product containing 108 cfu/ml of Yoplait-Al strain were 100 times higher than the concentrations after ingestion of a control meal the passage lasted for more than 5 hr and no permanent colonization of the small bowel was observed. Reported studies in healthy volunteers ingesting different probiotic preparations showed that fecal concentrations of L. acidophilus, 106 cfu/g.

In reported study two main hexose fermentation pathways are used to classify LAB genera. Under conditions of excess glucose and limited oxygen, homolactic LAB catabolize one mole of glucose in the Embden-Meyerhof-Parnas pathway to yield two moles of pyruvate. Intracellular redox balance is maintained through the oxidation of NADH, concomitant with pyruvate reduction to lactic acid. This process yields two moles of ATP per mole of glucose consumed.

Heterofermentative LAB use the pentose phosphate pathway, alternatively referred to as the pentose phosphoketolase pathway. One mole of glucose-6-phosphate is initially dehydrogenated to 6-phosphogluconate and subsequently decarboxylated to yield one mole of CO2. The resulting pentose-5-phosphate is cleaved into one mole glyceraldehyde phosphate (GAP) and one mole acetyl phosphate. GAP is further metabolized to lactate as in homofermentation, with the acetyl phosphate reduced to ethanol via acetylCoA and acetaldehyde intermediates. In theory, end products (including ATP) are produced in equimolar quantities from the catabolism of one mole of glucose.

6. Nonclinical properties

6.1. Animal Toxicology or Pharmacology

Not Applicable.

7. Description

Zinc is a mineral that is present naturally in the food. Zinc is an element with atomic symbol Zn, atomic number 30, and atomic weight 65.38.

Vizylac DT

Lactic Acid Bacillus and Zinc Sulphate Monohydrate tablets are white to off-white, round bevel edged, flat tablet with break line on one side and plain on other side.

The excipients used are Microcrystalline Cellulose, Aerosil, Aspartame, Cross Carmellose Sodium, Cross Povidone, 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 DT is packed in Pack of 10 tablets.

8.4. Storage and handing instructions

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

Keep out of reach of children.

Direction for use : Disperse the tablets in a teaspoonful of previously boiled and cooled water before administration.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies
- Have kidney or liver problems
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illness
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

10. Details of manufacturer

Uni Medicolabs

Plot No. 21-22, Pharmacity,

Selaqui, Dehradun- 248011,

Uttarakhand, India.

11. Details of permission or licence number with date

Mfg. Lic. No. is 55/UA/SC/P-2008. Issue on 12.12.2024.

12. Date of revision

APR 2026

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/VIZYLAC DT 120x10^6, 10 mg /APR-2026/03/PI