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 …Not less than 120 million spores (120 x 10^6 spores)
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, Flavour Pineapple 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

For the treatment of Diarrhea

4.2 Posology and method of administration

Dosage: As directed by the Physician.

Direction for use: 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 long-term treatment (e.g. if zinc deficiency is no longer present) and/or with higher doses of zinc.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactionsvia any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

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

Zink 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.Pharmacodynamics 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 CO_2. 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 acetyl-CoA and acetaldehyde intermediates. In theory, end products (including ATP) are produced in equimolar quantities from the catabolism of one mole of glucose. Obligate Heterofermentative

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Note Applicable

7. Description

Vizylac DT 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, Flavour Pineapple and Magnesium Stearate.

8. Pharmaceutical particulars

8.1 Incompatibilities

None Stated

8.2 Shelf-life

Do not use later than the date of expiry.

8.3 Packaging information

Vizylac DT is packed in blister strips 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.

9. Patient Counselling Information

Read all of this leaflet carefully before you start using 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 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. See section 9.4.

What is in this leaflet?

9.1 What Vizylac DT are and what they are used for.

Vizylac DT contains active ingredient Lactic Acid Bacillus and Zinc Sulphate Monohydrate.

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.

Zinc sulfate monohydrate is a source of zinc, which is an essential trace element and involved in a number of body enzyme functions. Zinc Sulpahte is used to treat zinc deficiency and to treat dehydration. It is popularly used as a rehydration therapy among children suffering with diarrhea induced due to antibiotics.

Vizylac DT is indicated for the treatment of Diarrhea

9.2 What you need to know before you use Vizylac DT

Do not use Vizylac DT:

- If you are allergic to Lactic Acid Bacillus and Zinc Sulphate Monohydrate or to any of the other ingredients of this medicine.
- Zinc may inhibit the absorption of copper so do not use Zinc if you suffer from Copper deficiency

Warning and Precautions

- Talk to your doctor, pharmacist or nurse before taking Vizylac DT if you suffer from kidney disease. Accumulation of zinc may occur in cases of renal failure.
- This product contains sodium. Therefore you should consult your doctor if you are on a controlled sodium diet.

If this applies to you it is important that you tell your doctor or pharmacist before taking Vizylac DT and they will decide what to do. It may still be safe for you to take Vizylac DT.

Make sure to tell about the allergy and what signs you had. This includes telling about rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking or have recently taken any of the following:

- Copper supplements
- Tetracycline antibiotics (such as oxytetracycline or doxycycline) used to treat certain bacterial infections
- Quinolone antibiotics (such as ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin) used to treat certain bacterial infections
- calcium salt preparations
- Iron preparations
- Penicillamine (used to treat rheumatoid arthritis, Wilson's disease, autoimmune hepatitis and cystinuria)
- Trientine (used in the treatment of Wilson's disease)
- Inform your doctor if you are on antibiotics, Biotin, Barbiturates, Chlorpromazine, Carbamazepine, Atropine, and Ciprofloxacin during the treatment.

Vizylac DT with food and drink

Vizylac DT should be taken after meals.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you should not take these tablets. Ask your healthcare provider for advice before taking any medicine. As the safety of Vizylac DT in human pregnancy is not known. Vizylac DT contains Zinc and it has been shown to cross the placenta and is present in breast milk in females taking zinc supplements. Only take this product during pregnancy or while breast-feeding if your doctor has advised you to do so. Ask your doctor or

pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

Driving and using machines
Vizylac DT is not expected to affect the ability to drive or use machines. However do not drive or operate machinery until you know how this product affects you.

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

9.3 How to use Vizylac DT
Always take this medicine exactly as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure. Vizylac DT should be taken orally

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

How much will be given
Your health care provider will decide how much to give you.

If you take more tablets than you should
If you take too many tablets, contact your nearest hospital casualty department or doctor immediately. Take this leaflet and any remaining tablets with you to show the doctor.

Signs of a very bad reaction to the drug. These include wheezing; chest tightness; fever; itching; bad cough; blue or gray skin color; seizures; or swelling of face, lips, tongue, or throat. Any rash. Side effect or health problem is not better or you are feeling worse.

If you forget to take Vizylac DT
If you forget to take your tablets, take them as soon as you remember and then continue with the next dose as instructed. Do not take a double dose to make up for a forgotten dose.

If you stop taking Vizylac DT
To get the most benefit from Vizylac DT**,** always finish the course of treatment recommended by your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

9.4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been reported:

- Reduced copper levels, potentially leading to copper deficiency
- Abdominal pain
- Indigestion
- Nausea (feeling sick)
- Vomiting (being sick)
- Diarrhoea
- Stomach discomfort
- Irritability
- Headache
- Lethargy (a feeling of weariness)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:
- Loss of appetite

- Altered sleep patterns
- Skin rashes
- Irritability

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 DT

Store in a cool & dry place. Protect from light & moisture. Keep all medicines out of reach of children.

9.6 Contents of the pack and other information

Each dispersible uncoated tablet contains as active ingredients Lactic Acid Bacillus 120 x 10^6 and Zinc Sulphate Monohydrate I.P. 10 mg

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

Vizylac DT is packed in blister strips of 10 tablets

10. Details of Manufacturer

Uni Medicolabs

Plot No. 25-26 Pharmacity, Selaqui, Dehradun, and Uttarakhand.

11. Details of permission or licence number with date

31/UA/SC/P-2018 issued on 28.10.2009

12. Date of revision

Not applicable

MARKETED BY

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IN/VIZYLAC DT 120x10^6, 10 mg /OCT-23/02/PI