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

VIZYLAC RICH SACHET

1. Generic Name

Probiotic-Prebiotic & lmmunobiotic Powder

2. Qualitative and quantitative composition

Each 1.0 g Sachet contains:

Streptococcus faecalis……..30 Million

Clostridium butyricum…….2 Million

Bacillus mesentericus……..1 Million

Lactobacillus sporogenes…….50 Million

Saccharomyces boulardii……..50 Million

Colour: Sunset Yellow FCF

The excipient used is Maltodextrin.

3. Dosage form and strength

Dosage Form: Granules

Strength: 30 Million + 2 Million + 1 Million + 50 Million + 50 Million

4. Clinical particulars

4.1 Therapeutic indication

- Treatment and prevention of antibiotic associated diarrhoea (AAD).
- Prevention of acute infectious diarrhoea, *Clostridium difficile* associated diarrhoea and nosocomial diarrhoea in children.
- Adjuvant therapy for children diarrhoea, acute diarrhoea in adults, *Clostridium difficile* associated diarrhoea, eradication of H. pylori infection, mediation induced diarrhoea, inflammatory diseases (Inflammatory bowel disease, Inflammatory bowel syndrome), non-alcoholic fatty liver disease and hepatic encephalopathy.

4.2 Posology and method of administration

One sachet thrice daily or as directed by the physician.

4.3 Contraindications

- Hypersensitivity to any of the ingredients
- Hypersensitivity to lactose or milk
- Immunocompromised state

4.4 Special warnings and precautions for use

Caution should be exercised in:

- Patients sensitive to milk should not use lactobacillus products

- Use in severely ill and malnourished children
- Use in severely ill adults having terminal illness.

4.5 Drugs interactions

No data available.

4.6 Use in special populations (Such as Pregnant Women, Lactating Women, Paediatric Patients, Geriatric Patients Etc.)

Pregnancy and lactation

There are no adequate and well controlled studies of this FDC during pregnancy and lactation. FDC should be used during pregnancy only if the potential benefit justified the potential risk to the foetus.

Caution should be exercised during breast feeding because it is not known whether any of the component of this FDC is excreted in human breast milk.

4.7 Effects on ability to drive and use machines

No data available.

4.8 Undesirable effects

The undesirable effects are as follows:

Constipation, gas, bloating, itching, hiccups, urticaria, exanthema, quincke's edema and systemic mycosis have been reported.

Chest pain, endocarditis, septicemia have been reported during treatment However, it is unknown whether this symptom was due to probiotic therapy or to concomitant antibiotic therapy.

4.9 Overdose

In the event of over dosage, supportive and symptomatic therapy is indicated.

5. Pharmacological properties

5.1 Mechanism of Action

***Streptococcus faecalis*-** colonizes the human gut and helps in normalization of gut flora, stimulation of mucosal immunity and prevention of diarrhoea, inflammatory diseases and lactose intolerance.

***Clostridium butyricum*-** on proliferation, yields short chain fatly acids (SCFA} such as butyric acid and acetic acid with a resultant decrease in intestinal pH.

***Bacillus mesentericus*-** Selectively stimulate the growth of beneficial anaerobic bacteria and inhibits the growth of pathogenic bacteria. It also helps to decrease secretion of luminal enterotoxin.

***Lactobacillus sporogenes*-** In intestinal tract by producing lactic acid and bacteriocin, *Lactobacillius sporogens* makes unfavourable and non-conducive environment for the growth of harmful pathogenic bacteria. By maintaining constant low level of lactic acid on the inner surface of the intestinal tract, it helps to restore the normal microecological balance after antibiotic therapy.

Reported possible mechanisms for the effective action of lactobacilli in the treatment of various gastrointestinal (GI) tract pathologies include replacement of pathogenic

organisms in the GI tract by lactobacilli, elicitation of an immune response, lowering of fecal pH, and interfering with the ability of pathogenic bacteria to adhere to intestinal mucosal cells.

Saccharomyces boulardii- The exact mechanism of *Saccharomyces boulardii* is not clearly defined. With *Saccharomyces boulardii* antagonist activity against bacterial pathogens and candida has been reported. Reported increase in disaccharide activity of intestinal mucosa may improve carbohydrate absorption and enterocyte metabolism. In C. difficile infection, it may exert beneficial effects via interference in colonization or production of protease. It may exert a protective effect in the gastrointestinal tract via stimulation of the intestinal secretion of secretory IgA. The mechanism of its action against cholera toxin reported to be mediated by a specific yeast protein and involves a receptor that is negatively coupled to adenylate cyclase.

5.2 Pharmacodynamic properties

Beneficial bacteria are the natural inhabitant of human gastrointestinal tract. Their presence in gastrointestinal tract helps to prevent colonization by pathogenic bacteria. Often, antibiotic use or dysregulated immune responses deplete these normal beneficial bacteria and cause growth of pathogenic bacteria. This intestinal dysbiosis leads to development of various gastrointestinal disorders.

In dysbiosis, beneficial probiotic bacteria and yeast assist body to restore normal balance of gut flora and help to prevent and treat dysbiosis related gastrointestinal disorder.

Probiotic beneficial effect reported in numerous gastrointestinal disorders. Beneficial effect of probiotics noted in prevention of diarrhoea caused by antibiotics or as part of the treatment for antibiotic-related dysbiosis.

Reportedly, clinical studies also noted beneficial effects on a variety of gastrointestinal and extra intestinal disorders, including inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), vaginal infections, and immune enhancement. Beneficial probiotic effects are restricted to specific species and strain.

Streptococcus faecalis

Streptococcus faecalis is a Gram~positive bacterium and belongs to the lactic acid bacteria group. In addition to being gram-positive, it is also a commensal bacterium that lives in a mammal's gastrointestinal tract and reclassified as *Entarococcus faecalis*.

Clostridium butyricum

Clostridium butyricum is a Gram-positive, anaerobic, spore forming bacterium. It is found in the region from the upper small Intestine to the colon. On proliferation, it yields short chain fatly acids (SCFA} such as butyric acid and acetic acid with a resultant decrease in intestinal pH.

Clostridium butyricum helps in digestion, bowel movement, growth of beneficial bacteria (Bifidobacteria), and integrity of the gastrointestinal tract mucosa.

Bacillus mesentericus

It is Gram-positive bacteria which selectively stimulate the growth of beneficial anaerobic bacteria and inhibit the growth of pathogenic bacteria.

Lactobacillus sporogenes

Lactobacillus sporogenes also known as *Bacillus coagulena* is a Gram-positive, lactic-acid producing and spore-forming bacteria. The property of spore formation makes it the probiotic of choice in clinical applications. In intestinal tract by producing lactic acid and bacteriocin, *Lactobacillius sporogenes* makes unfavourable and non-conducive environment for the growth of harmful pathogenic bacteria. By maintaining constant low level of lactic acid on the inner surface of the intestinal tract, it helps to restore the normal microecological balance after antibiotic therapy.

Saccharomyces boulardii

S. boulardii belongs to the group of simple eukaryotic cells (such as fungi and algae) and it thus differs from bacterial probiotics that are prokaryotes. Property of optimum growth temperature at 37°C, resistant to low pH and tolerant to bile acids make it an ideal probiotic agent. Reportedly, it is the only yeast probiotic that has been proven efficacy in number of clinical studies. It is commonly used both in prevention and treatment of diarrhoea and other GI disorders caused by the administration of antibacterial agents.

5.3 Pharmacokinetic properties

Saccharomyces boulardii reached steady state after 72 hours of administration and rapidly eliminated by other routes with less than 1% recovered in faeces.

No pharmacokinetics data available for other species like *Streptococcus faecalis, Bacillus mesentericus, Clostridium butyricum and Lactobacillus sporogenes*.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

No data available.

7. Description

VIZYLAC RICH SACHET is fixed dose combination of *Streptococcus faecalis, Bacillus mesentericus, Clostridium butyricum and Lactobacillus sporogenes*. This is a unique probiotic fixed dose combination of multi-species bacteria and yeast for treatment of diarrhoea (infantile, traveler's, antibiotic-induced and Clostridium difficile) and other gastrointestinal pathologies {Inflammatory diseases, *Helicobacter pylori* eradication).

Probiotic-Prebiotic & Immunobiotic powder is sachet containing white to off white coloured powder. The excipient used is Maltodextrin.

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 RICH SACHET is available in 1 g Sachet.

8.4 Storage and handing instructions

Store below 25°C. Protect from light and moisture.

Keep all medicines 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.

What is in this leaflet:

9.1 What VIZYLAC RICH SACHET is and what it is used for

VIZYLAC RICH SACHET is a unique probiotic fixed dose combination of multi-species bacteria and yeast for treatment of diarrhoea (infantile, traveler's, antibiotic-induced and Clostridium difficile) and other gastrointestinal pathologies {Inflammatory diseases, *Helicobacter pylori* eradication).

VIZYLAC RICH SACHET is used:

- In the treatment and prevention of antibiotic associated diarrhoea (AAD).
- Prevention of acute infectious diarrhoea, *Clostridium difficile* associated diarrhoea and nosocomial diarrhoea in children.
- Adjuvant therapy for children diarrhoea, acute diarrhoea in adults, *Clostridium difficile* associated diarrhoea, eradication of *H. pylori* infection, mediation induced diarrhoea, inflammatory diseases (Inflammatory bowel disease, Inflammatory bowel syndrome), non-alcoholic fatty liver disease and hepatic encephalopathy.

9.2 What you need to know before you use VIZYLAC RICH SACHET

Do not take VIZYLAC RICH SACHET if:

- You have hypersensitivity to any of the ingredients of this product
- You are sensitive to milk (you should not use lactobacillus products)
- You have an impaired immune system

Warnings and precautions

Care should be taken:

- If it is used in severely ill and malnourished children
- If it is used in severely ill adults having terminal illness

It should be cautiously used if you have liver disease

It should be cautiously used if you have kidney disease

Children and adolescents

Caution should be exercised if it is used in severely ill and malnourished children

Pregnancy and breast-feeding

Pregnancy

It should be used only if the potential benefit justified the potential risk to the foetus.

Breast-feeding

Caution should be exercised during breast feeding because it is not known whether any of the component of this product is excreted in human breast milk.

Hepatic and Renal Impairment

There are no data available regarding use of VIZYLAC RICH SACHET in this population. Hence, caution should be exercised.

9.3 How to use VIZYLAC RICH SACHET

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

If you take more VIZYLAC RICH SACHET than you should

If you accidentally take too much amount of VIZYLAC RICH SACHET, you must contact your doctor and take supportive and symptomatic therapy.

If you forget to take VIZYLAC RICH SACHET

If you forget to take a dose, do not worry. Take it as soon as you remember, then carry on as before. If you do not take your dose on one day, take your normal dose on the next day. Do not take a double dose to make up for a forgotten dose.

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

9.4 Possible Side Effects

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

Some side effects can be serious and need immediate medical attention

You should see your doctor if you experience any of the following symptoms:

- Constipation
- Gas
- Bloating
- Itching

- Hiccups
- Urticaria (Hives)
- Exanthema
- Quincke's edema (Angioedema)
- Systemic mycosis (Fungal infection)

You may also experience any of the following symptoms but they may not be necessarily associated with VIZYLAC RICH SACHET.

9.5 How to store VIZYLAC RICH SACHET

Store below 25°C. Protect from light and moisture.

Keep this medicine out of the sight and reach of children.

9.6 Contents of the pack and other information

What VIZYLAC RICH SACHET contains:

• The active substances are *Streptococcus faecalis, Bacillus mesentericus, Clostridium butyricum, Lactobacillus sporogenes* and *Saccharomyces boulardii*. Each capsule contains 30 Million of *Streptococcus faecalis,* 2 Million of *Clostridium butyricum,* 1 Million of *Bacillus mesentericus,* 50 Million of *Lactobacillus sporogenes,* 50 Million of *Saccharomyces boulardii*.

• The excipient used is Maltodextrin.

What VIZYLAC RICH looks like and contents of the pack

Pack Sizes

VIZYLAC RICH SACHET is available in 1 g Sachet.

10. Details of manufacturer

Manufactured in India by:

Ordain Health Care Global Pvt. Ltd.

532, Uthiramerur Road, Melavalampettal, Karunguzhi – 603 303,

Kanchipuram District, Tamil Nadu.

11. Details of permission or licence number with date

Mfg Lic No. TN00003297 issued on 01.03.2014.

12. Date of revision

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MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/VIZYLAC RICH SACHET 30, 2, 1, 50, 50 Million/APR-2020/01/PI