

NPN 80013321

Probiotic for Effective Relief of Diarrhea, 10 or 50 cap

PHARMACOLOGY: *Saccharomyces boulardii lyo* is ingested and reaches the small and large intestine in a viable state. Under normal conditions the cells do not enter into the circulatory system. *Saccharomyces boulardii lyo* does not permanently colonize the human intestinal tract. Bacteria exert their pathogenicity via toxins in the intestines.

Saccharomyces boulardii lyo secretes a 54 kDa protein protease that neutralizes toxins secreted by bacteria. Some bacteria produce toxins that increase the intracellular level of cyclic adenosine monophosphate (cAMP) by activating the adenylate cyclase in intestinal epithelial cells. This triggers active secretion of chloride and bicarbonate resulting in diarrhea. In studies, *Saccharomyces boulardii lyo* inhibited approximately 50% of the water and sodium secretion caused by cholera toxin (CT) compared with loops treated with CT alone. Toxins A and B secreted by *Clostridium difficile* are reduced by a factor of 100 to 1000 in mice treated with *Saccharomyces boulardii lyo*. *Saccharomyces boulardii lyo* increases the absorptive transport of chloride in intestinal electrolyte transport. *Saccharomyces boulardii lyo* releases polyamines (spermine, spermidine and putrescine) which help increase the activity of disaccharidase enzymes (lactase, sucrase and maltase). *Saccharomyces boulardii lyo* also stimulates production of IgA and IgG in the intestinal mucosa which may help decrease the effects of the toxins.

RECOMMENDED USE OR PURPOSE:

Helps to reduce the risk of antibiotic associated diarrhea in adults. Helps reduce the symptoms related to acute diarrhea (infectious) in adults. Helps to treat acute diarrhea (infectious) in children.

CONTRAINDICATIONS: Do not use if you have hypersensitivity to any component of the product (especially allergy to yeast) or if you have a central venous catheter.

CAUTIONS AND WARNINGS: Discontinue use and consult a health care practitioner if symptoms of digestive upset (e.g. diarrhea) occur, worsen or persist beyond 3 days. Avoid opening the capsules in the presence of patients having a central venous catheter. May exacerbate lactose intolerance. Do not use if you have an immune-compromised condition (e.g. AIDS, lymphoma, long-term corticosteroid treatment). Consult a health care practitioner prior to use if you have an abnormal condition of the gastrointestinal tract lining (i.e. ulcer or other GI tract disorders). Do not use if you are experiencing nausea, fever, vomiting, bloody diarrhea or severe abdominal pain. Treatment does not replace rehydration when this is necessary.

PREGNANCY AND NURSING

MOTHERS: There are no adequate and well-controlled studies in pregnant women. It is classified as Pregnancy category B.

Saccharomyces boulardii lyo is not excreted in human milk. However, caution should be exercised when *Saccharomyces boulardii lyo* is given to nursing women.

KNOWN ADVERSE REACTIONS:

Rarely: flatulence, pruritus, rash, angioedema. Very rarely: anaphylactic

reaction.

DOSAGE AND ADMINISTRATION:

Florastor® is to be taken orally. Capsules should be swallowed in its entirety and not chewed. The contents of capsules may be ingested directly or mixed with a favourite food or drink.

DOSING:

Children: (1-12 years): Take 1 capsule twice a day for 1 week.

Adults: Take 1 capsule twice a day for 1 week (may increase the dose to a maximum of 6 capsules a day if recommended by a health care practitioner)

* treatment does not replace rehydration when this is necessary

OVERDOSE: No overdoses have been reported with *Saccharomyces boulardii lyo*. In the event of overdose, patients should be carefully observed and given supportive treatment.

SUPPLIED:

The yeast cells in Florastor® *Saccharomyces boulardii lyo* are in the form of a lyophilized powder.

One capsule of Florastor® contains: 5×10^9 CFU (equivalent to 250 mg) of *Saccharomyces Boulardii*

32.50 mg of lactose monohydrate

2.85 mg of magnesium distearate

gelatin

Outer shell contains:

hypromellose

colouring: titanium dioxide

E171

Florastor® is gluten and wheat free.

STORAGE:

Do not use if seal is broken. Store at 15-30°C in a dry area. No need to refrigerate

