

ACTIFLOR®

(*Saccharomyces boulardii* 250mg Sachet)

ایکٹی فلور

SUPPLEMENT FACTS

Actiflor Sachet:

Each ACTIFLOR sachet contains:

Saccharomyces boulardii.....250 mg (Lyophilized)
(Pharvevo Specs.)

DESCRIPTION

ACTIFLOR sachet contains *Saccharomyces boulardii* which is a specific form of live yeast (a type of fungus) that has been lyophilized (freeze dried). It is extensively used internationally as a probiotic to treat diarrheal illnesses and promote intestinal health. Probiotics are live microorganisms that, when administered in adequate amounts, confer a health benefit to the host.

PHARMACOLOGICAL PROPERTIES

Mechanism of action

Saccharomyces boulardii has been used as a probiotic or "friendly germ," to treat diarrheal illnesses, maintain normal bowel function and promote intestinal health. *Saccharomyces boulardii* may work by helping the body maintain normal consistency of bacteria in the intestines. It restores normal bowel flora that inhibit growth of harmful bacteria; stimulates local immunity; promotes water reabsorption in colon.

It has been shown to offer in vitro and in-vivo microbial antagonism against *E.coli*, *Salmonella* and *Shigella* species which are among the most commonly encountered bacterial pathogens in diarrheal illness.

It also induces a significant increase in the concentration of the secretory components and immunoglobulin A (IgA) – the first line of defense against infection in the GI tract.

It also reduces the enterotoxic effects of bacterial toxins by inhibiting toxin receptor binding sites. It may also cause a significant increase of disaccharidases including lactase, sucrase and maltase.

THERAPEUTIC EFFECTS

- Treatment and prevention of diarrhea, including viral types such as rota-viral diarrhea in children
- Treatment and prevention of diarrhea caused by overgrowth of gastrointestinal bad bacteria or caused by use of antibiotics including *Clostridium difficile* associated diarrhea (CDAD) and recurring *Clostridium difficile* associated colitis.
- Treatment of traveler's diarrhea and diarrhea associated with tube feedings.
- Treatment of diarrhea associated with Irritable Bowel Syndrome (IBS), Inflammato-

tory Bowel Disease (IBD) including Crohn's disease and Ulcerative Colitis, and bacterial overgrowth in Short bowel syndrome.

DOSAGE AND ADMINISTRATION

General dosage:

Adults: 1-2 sachets of ACTIFLOR (250-500 mg of *S.boulardii*) twice daily for all types and variants of diarrhea.

Pediatric: It is advisable to use 1 sachet of ACTIFLOR (250 mg of *S.boulardii*) twice daily in infants and children.

Note: Dosing recommendations for specific types of diarrhea given below may also be followed.

For diarrhea associated with the use of antibiotics:

- 1-2 sachets of ACTIFLOR (250-500 mg of *S.boulardii*) two to four times a day.

For diarrhea caused by *Clostridium difficile*:

- 1 sachet of ACTIFLOR (250 mg of *S.boulardii*) four times a day for 4 weeks along with standard antibiotic treatment.

For Crohn's disease:

- 1 sachet of ACTIFLOR (250 mg of *S.boulardii*) four times a day in combination with usual treatment has also been used.

For ulcerative colitis:

- 1 sachet of ACTIFLOR (250 mg of *S.boulardii*) three times daily.

Administration requirements

Pour the contents of the sachet in at least 4 ounces of water beverage or semi liquid, mix and swallow. ACTIFLOR should not be mixed with very cold or very hot liquid or food.

CONTRAINDICATIONS

- Immunocompromised patients
- GI wall perforation
- Patients allergic to yeast or yeast-based products
- Patients taking systemic antifungals (This will lead to loss of efficacy of *S.boulardii*)
- Critically ill patients and patients having central venous catheters

WARNINGS AND PRECAUTIONS

S.boulardii induced fungemia

Saccharomyces fungemia and invasive *Saccharomyces* infection secondary to use of *S.boulardii* has been reported for patients that are critically ill, are receiving nutrition enterally, or have central venous catheters. Other risk factors for fungemia include immune-compromised patients and patients on immunosuppressant drugs. Though reported rarely *Saccharomyces* fungemia can be serious.

S. boulardii administration may also present an environmental risk for catching fungemia for other patients in critical care settings who are not receiving these

agents due to substantial air contamination resulting from opening of the sachets.

Other factors that constitute a risk for development of *Saccharomyces* fungemia in institutional settings via environmental contamination include the potential for live yeast spore contamination of healthcare workers' hands during opening of the sachet for administration, and introduction of live yeast from contaminated hands to catheter sites (and patient's bloodstream).

Institutional guidelines are needed to address the potential safety issues related to *S. boulardii* use. After the decision is made to use *S. boulardii* on the basis of careful risk assessment, the following measures should be taken: 1) healthcare providers should wear gloves during the handling of probiotic agents for administration, then promptly discard the gloves and properly wash their hands with soap and water, 2) sachets should not be opened near patients with central venous catheters because aerosolized spores could cross-contaminate sterile sites (i.e., enter blood through catheter site) of patients receiving the probiotic as well as other patients nearby.

S. boulardii administration does not present any risk of fungemia to out-patients except those with severe immunosuppression.

Yeast allergy

People with yeast allergy can be allergic to products containing *Saccharomyces boulardii*, and must not use these products.

Treatment of *Clostridium difficile* associated diarrhea and relapsing colitis

S. boulardii should not be used to treat *C. diff* associated colitis/diarrhea as monotherapy. It must always be used in combination with standard antimicrobial therapy recommended for *C. diff* therapy. In combination with vancomycin or metronidazole *S. boulardii* has been shown to reduce the recurrence rates of *C. diff* associated diarrhea and colitis.

ADVERSE REACTIONS

Rare: Fungemia, serious allergic reactions: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.
Uncommon: Constipation, Flatulence, bloating, increased thirst.

DRUG INTERACTIONS

Use of systemic antifungals such as fluconazole, itraconazole, terbinafine with *S. boulardii* supplements causes loss of efficacy of *S. boulardii*. Concomitant use is not recommended.

USE IN SPECIAL POPULATIONS

Pregnancy

There is not enough reliable information about the safety of taking *Saccharomyces boulardii* in pregnancy. Avoid use.

Nursing mothers

There is not enough reliable information about the safety of taking *Saccharomyces boulardii* during breast feeding. Avoid use.

Pediatrics

Saccharomyces boulardii can be used for infants and children. However, diarrhea in children should be evaluated by a healthcare professional before using *S. boulardii*. Replacement of water and electrolytes is recommended.

PRESENTATION

Pack of 10 Sachets.

INSTRUCTIONS

As advised by the physician.
Keep all medicines out of the reach of children.
To be sold on the prescription of a registered medical practitioner only.
Protect from heat, light and moisture.
Store below 30°C.

For more information on our products
call PharmAssist helpline 0800-82222
Monday to Friday 9:00 am to 6:00 pm
or email us at : pharmassist@pharmevo.biz

خوراک: ایک سے دوسرے، روزانہ ایک سے دوسرے
طریقہ استعمال: ساشے میں موجود پاؤڈر (سکرو مائیں بولا ری) کو پانی، مٹھا یا رقیق
(تکلی) تھامیں ملائیں اور پی لیں یا کھالیں۔
ہدایات: ایکٹیو فلور کو بہت ٹھنڈی یا بہت گرم (مٹھا یا تھانڈا) کے ساتھ نہیں ملانا چاہیے۔
ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخہ پر ہی فروخت کی جائے۔
روشنی، گرمی اور نمی سے محفوظ، 30°C سے کم درجہ حرارت پر رکھیں۔

PharmEvo
Our dream, a healthier society

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