

# Sacrospa Sachet

## Composition

Each sachet contains:

Lyophilized *Saccharomyces boulardii*..... 250 mg/ 1 gm

(equivalent to 250 mg of yeast *Saccharomyces boulardii*)

Excipients ..... q.s.

Flavours: Orange.

## Overview

Acute diarrhoea kills more than 1.5 million children below 5 years of age every year globally, and is the second most common cause of death in this age group. Acute diarrhoea in children is, largely, of viral origin and the commonest agent, worldwide, is rotavirus. The mainstay of treatment of an acute diarrhoea episode includes oral rehydration therapy (ORT) and zinc, including probiotics. ORT aims to prevent or reverse dehydration, and has no effect either on the duration of diarrhoea or on the stool output. Zinc, too, is not universally effective in the treatment of acute diarrhoea and is just used to build up the immunity. For this reason, various other medications (e.g. loperamide, diosmectite) have been studied in the treatment of acute childhood diarrhoea, but the effects are neither consistent nor supported by the evidence.

Probiotics are defined as “live microorganisms that confer health benefits on the host when administered in adequate amounts.” An increasing number of potential health benefits are being attributed to probiotic treatments. They have been studied in many paediatric diseases, including acute childhood diarrhoea. There are different probiotic strains available in the market, but the efficacy and safety of *Lactobacillus GG* and *Saccharomyces boulardii* has been consistently established in acute childhood diarrhoea.

SACROSPA Sachet contains *Saccharomyces boulardii*, which is non-pathogenic yeast that has demonstrated an anti-inflammatory, antimicrobial, enzymatic, metabolic and anti-toxin activity, including a trophic effect, by enhancing the metabolic function of the gut mucosa. *Saccharomyces boulardii* has been prescribed over the last 30 years for prophylaxis and treatment of diarrhoeal diseases caused by different infectious agents.

Importantly, *Saccharomyces boulardii* has demonstrated clinical and experimental effectiveness in gastrointestinal diseases with a predominant inflammatory component, indicating that this probiotic might interfere with cellular signalling pathways common in many inflammatory conditions.

*Saccharomyces boulardii* is shown to be safe and to reduce the duration of diarrhoea and hospitalization and is recommended by the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN)/ESPID/ AAP. *S. boulardii* is one of the recommended probiotics for the prevention of antibiotic-associated diarrhoea.

SACROSPA Sachet is indicated for the treatment of acute infectious diarrhoea in adults and children, prevention and treatment of antibiotics-associated colitis and diarrhoea, and as an addition to vancomycin/metronidazole-treatment to prevent the recurrence of *Clostridium difficile* diseases. SACROSPA Sachet comes in a sachet and it contains lyophilized *Saccharomyces boulardii* equivalent to 250 mg of yeast *Saccharomyces boulardii*, and is available in orange and vanilla flavours. The recommended dosage is one to two sachets to be given twice daily or as directed by the physician. SACROSPA Sachet should be administered orally, directly or mixed with water (5–10 ml) or a beverage, or in a baby's feeding bottle. The contents of the sachet should not be mixed in very cold or hot liquids or food.

### **Composition**

SACROSPA Sachet

Each sachet contains:

Lyophilized *Saccharomyces boulardii*..... 250 mg/1 gm

(equivalent to 250 mg of yeast *Saccharomyces boulardii*)

Excipients ..... q.s.

Flavours: Orange.

### **Dosage form**

Dry powder.

### **Pharmacology**

## **Pharmacodynamics**

Saccharomyces boulardii acts by inhibiting the pathogenic effects of certain micro-organism and/or their toxins, especially Clostridium difficile, the principle causative organism in antibiotic-associated diarrhoea, and Vibrio cholerae, typical of the toxin-producing bacterium responsible for secretory diarrhoea.

Saccharomyces boulardii exerts a trophic and immune stimulant effects on the intestinal tract involving notable and significant increase in the total and specific activity of the intestinal disaccharidases (sucrase, maltase and lactase), and marked increase in secretory IgA concentrations in the intestinal fluid.

## **Pharmacokinetics**

Saccharomyces boulardii, after repeated oral doses, transits in the digestive tract without colonizing it, rapidly attaining significant intestinal concentrations, which are maintained at a constant level throughout the administration period. The capsule dissolves in the stomach and releases the yeast cells within 30 minutes of ingestion. The cells are spread throughout the small and large intestines, creating a barrier in the gut against bad bacteria. Saccharomyces boulardii is not present in the stools 2–5 days after discontinuation of treatment.

## **Indications**

SACROSPA Sachet is indicated for the treatment of acute infectious diarrhoea in adults and children, prevention and treatment of antibiotics-associated colitis and diarrhoea, and as an addition to vancomycin/metronidazole-treatment to prevent the recurrence of Clostridium difficile diseases.

## **Dosage and Administration**

### **Dosage**

One to two sachets to be given twice daily or as directed by the physician.

### **Administration**

SACROSPA Sachet should be administered orally, directly or mixed with water (5–10 ml) or a beverage, or in a baby's feeding bottle. The contents of the sachet should not be mixed in very cold or hot liquids or food.

## **Contraindications**

SACROSPA Sachet is contraindicated in patients with a known hypersensitivity to any of the ingredients of the formulation or yeast allergy. SACROSPA Sachet is contraindicated in patients with central venous catheter. SACROSPA Sachet is contraindicated during pregnancy and lactation.

## **Warnings and Precautions**

### **General**

SACROSPA Sachet contains living cells and, therefore, it should not be mixed with very hot (over 50°C), iced or alcoholic drinks or food.

The treatment with *Saccharomyces boulardii* does not replace rehydration. The patient should be appropriately rehydrated based on the severity of diarrhoea, age and the state of health of the patient.

SACROSPA Sachet contains a small amount of lactose, but has been successfully taken by people who cannot eat lactose. Even so, caution is advised and it is usually contraindicated in patients with congenital lactose intolerance.

### **Drug Interactions**

SACROSPA Sachet should not be administered with systemic or oral antifungal drugs, because of the fungal nature of this formulation.

### **Use in Special Population**

#### **Pregnancy**

The safety and efficacy has not been established in pregnant women.

#### **Lactation**

The safety and efficacy has not been established in nursing mothers.

### **Undesirable Effects**

Gas, constipation and thirst have been reported infrequently. Very rare cases of fungaemia with fever and positive haemoculture for *Saccharomyces* have been reported in hospitalized patients with a central venous catheter, in immunocompromised patients, in patients with gastrointestinal disease, or in patients treated with high dosage.

### **Overdosage**

Very rare cases of fungemia have been reported in patients on high or over dosage, however in all the cases the course was favourable after an antifungal treatment.

### **Storage and Handling Instructions**

SACROSPA Sachet should be stored below 30°C and protected from light.

### **Sportine Technology**

Ensure *Saccharomyces boulardii* spores are protected by complex polysaccharides to prevent them from acid degradation. Polysaccharides coating dissolves and releases spores for multiplication on reaching small intestine.

6% population are having allergy from Gluten and sacrospa is available in Gluten Free sachet.

### **Packaging Information**

SACROSPA Sachet: 250 mg/ 1 gm sachet