

# SCHAROMYCES BOULARDI

## 1. Name of the medicinal product

Pronorm

## 2. Qualitative composition

Each sachet contains:

Lyophilised *Saccharomyces boulardii* 250 mg.

Excipients Q.S.

## 3. Pharmaceutical form

Powder

## 4. Clinical particulars

### 4.1 Therapeutic indications

*Saccharomyces Boulardii* 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.

### 4.2 Posology and method of administration

1 to 2 sachets can be directly consumed into the mouth or can be mixed with 20 ml of water not exceeding 30°C and consumed immediately. Do not mix with very hot or cold water.

### 4.3 Contraindications

- Product should not be given to those who are having allergy to any of its ingredients.
- 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

### 4.4 Special warnings and precautions for use

- If you have a surgical operation of abdominal cavity done during *Saccharomyces Boulardii* Sachets treatment, as there may be a risk of developing *Saccharomyces boulardii* sepsis.

- *Saccharomyces Boulardii* Sachets treatment does not replace the substitution of liquid lost with diarrhoea or rehydration, if this would be required.

Talk to your doctor or pharmacist before using *Saccharomyces Boulardii* Sachets. Children suffering from any disease should consult physician before taking the product.

### 4.5 Interaction with other medicinal products and other forms of interaction

As *Saccharomyces Boulardii* Sachets contains yeasts, it should not be administered together with antifungal medicines.

Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines.

#### **4.6 Fertility, pregnancy and lactation**

The medicine may be used during pregnancy and breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

#### **4.7 Effects on ability to drive and use machines**

Not Applicable

#### **4.8 Undesirable 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), Inflammatory Bowel Disease (IBD) including Crohn's disease and Ulcerative Colitis, and bacterial overgrowth in Short bowel syndrome.

#### **4.9 Overdose**

There are no data about overdosing.

### **5. 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.

#### **6.0 List of excipients**

- Anhydrous Glucose
- Sugar
- Sodium Saccharin
- Flavor Banana

#### **6.1 Incompatibilities**

None

#### **6.2 Shelf life**

24 Months

**6.3 Special precautions for storage**

This medicinal product does not require any special storage conditions.

**6.4 Nature and contents of container**

250 mg sachet (Laminate - PET/Aluminium/Poly)

**6.5 Special precautions for disposal and other handling**

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

**6. Marketing authorisation holder**

Malven Medics International Company Ltd  
Wilmer Street, Ilupeju Lagos.

**7. Marketing authorisation number(s)**

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