

**BIOGIT<sup>®</sup>**

Saccharomyces boulardii

  
**BHARAT**  
BIOTECH  
*Lead Innovation*

## **SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**



Saccharomyces boulardii

**1. NAME OF THE MEDICINAL PRODUCT:**

**Name of the product:** Saccharomyces boulardii

**Strength:**

Each Sachet contains:

Saccharomyces boulardii... 250.0 mg

Pharmaceutical Form: Granules

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION:**

Each Sachet contains:

Saccharomyces boulardii... 250.0 mg

Lactose..... 40.0 mg

D-Fructose..... 497.5 mg

Collodial Silica..... 7.5 mg

Artificial flavour..... 5.0 mg

**3. PHARMACEUTICAL FORM:**

**BIOGIT<sup>®</sup>** is a creamy white powder with brown coloured granules.

**4. CLINICAL PARTICULARS:**

**4.1 Therapeutic Indications:**

Saccharomyces boulardii is a live, non-pathogenic yeast recommended as a probiotic and biotherapeutic in treating diarrhoea of various etiology.

- Treatment of diarrhoea - Traveller's diarrhoea, viral diarrhoea in children and antibiotic associated diarrhoea.
- Treatment and prevention of digestive complications following antibiotic therapy: diarrhoea, colitis, candidiasis.
- Prevention of diarrhoea during continuous enteral feeding in adults.
- Prevention of vaginal yeast infections.

**4.2 Posology and method of administration:**

**Dosage:**

Adults & Children: 1 to 2 sachets twice daily or as directed by the physician.

**Directions for Use:**

**BIOGIT<sup>®</sup>** should be taken orally, directly or mixed with water or beverage. It should not be mixed in hot liquids or liquids which contain alcohol. **BIOGIT<sup>®</sup>** can be taken before or after food. For continuous enteral feeding, the drug may be added to the nutrient solution during preparation.

**4.3 Contraindications:**



Saccharomyces boulardii



*Saccharomyces boulardii* is sensitive to antifungal agents.

#### **4.4 Special warnings and precautions for use:**

Not Available

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

The interactions with other vaccines or medicinal products have not been established.

#### **4.6 Pregnancy and lactation:**

Safety and efficacy have not been established in pregnant women and in nursing mothers.

#### **4.7 Effect on the ability to drive and use machines:**

No studies on the effect of **BIOGIT**<sup>®</sup> on the ability to drive and use machines have been performed.

#### **4.8 Undesirable effects:**

Various clinical trials with *Saccharomyces boulardii* and post marketing surveillance studies have not shown any significant side-effects. Occasionally, a temporary increase in digestive gas is known to occur.

#### **4.9 Overdose:**

No case of overdose with **BIOGIT**<sup>®</sup> has been reported.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

*Saccharomyces boulardii* is a live, non-pathogenic yeast that is recommended as a probiotic and biotherapeutic in the treatment of diarrhoea of various etiology.

*Saccharomyces boulardii* favourably alters the composition of the gut flora and inhibits the action of pathogenic microorganisms. It maintains a healthy balance of intestinal flora by producing organic compound-such as lactic acid, hydrogen peroxide and acetic acid-that increase the acidity of the intestine and inhibit the reproduction of many harmful bacteria. Studies have revealed that it



Saccharomyces boulardii

also produces substances called bacteriocins, which act as natural antibiotics to kill undesirable microorganisms.

It synthesizes vitamin B1, vitamin B2, vitamin B6, pantothenic acid and nicotinic acid. These vitamins are utilized for the nutritional requirements of the body.

### **5.2 Pharmacokinetic properties**

Not Available.

### **5.3 Pre-clinical safety data**

Not Available.

## **6. PHARMACEUTICAL PARTICULARS:**

### **6.1 List of excipients:**

Lactose  
D-Fructose  
Collodial Silica  
Artificial flavour

### **6.2 Incompatibilities:**

This medicinal product must not be mixed with other medicinal products.

### **6.3 Shelf life:**

The Expiry date is indicated on the label and carton of the product.

### **6.4 Special precautions for storage:**

Store in a Cool, Dry Place. Keep out of reach of children.

### **6.5 Nature and contents of container:**

**BIOGIT**<sup>®</sup> is presented in Carton of 10 sachets

### **6.6 Special precautions for disposal**

Any unused product or waste material should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**



Saccharomyces boulardii



Bharat Biotech International Limited situated

Sy. No. 230, 231 & 235, Genome Valley,

Turkapally, Shamirpet Mandal,

Medchal, Malkajgiri District, Telangana State, India, Pin: 500078.

**8. MANUFACTURING LICENCE NUMBER**

13/RR/AP/2001/F&B/R

**9. DATE OF FIRST MANUFACTURING LICENCE**

20 FEB 2004

**10. DATE OF REVISION**

04 DEC 2020