
Prescribing information (Summary of Product Characteristics)

- **Name of the Medicinal Product:**

Brand Name: Flora Norm

Generic Name: *Saccharomyces boulardii*.

- **Pharmaceutical Form:** Fine granular powder.

- **Description:**

Saccharomyces boulardii is live, non-pathogenic yeast recommended as a probiotic and/or bio therapeutic in the treatment of diarrhoea of various etiology. *Saccharomyces boulardii* is manufactured using a highly controlled process. For better viability and increased shelf-life the yeast cells are granulized and formulated under strict GMP conditions. **Flora Norm** is a creamy white powder with brown coloured granules.

- **Qualitative and Quantitative Composition:**

Each sachet contains:

Saccharomyces boulardii 250.0 mg

D-Fructose 497.5 mg

Lactose 40.0 mg

Colloidal silica 7.5 mg

Artificial flavour 5.0 mg

- **Clinical Particulars**

Therapeutic indications:

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

Dosage and method of administration:

Flora Norm should be taken orally, directly or mixed with water or beverage.

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

Contraindications:

Saccharomyces boulardii is sensitive to antifungal agents.

Special warnings and precautions for use:

Flora Norm should not be mixed in hot liquids or liquids which contain alcohol.

Flora Norm can be taken before or after food. For continuous enteral feeding, the drug may be added to the nutrient solution at the time of preparation.

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.

- **Pharmacological Properties:**

Pharmacodynamic properties:

Not applicable.

Pharmacokinetic properties:

Not applicable

- **Pharmaceutical Particulars**

List of excipients:

D-Fructose	497.5 mg
Lactose	40.0 mg
Colloidal silica	7.5 mg
Artificial flavour	5.0 mg

Shelf life:

24 months from the date of manufacture.

Special precautions for storage:

Store in a cool and dry place. Keep out of reach of children.

Nature and contents of container:

The formulated bulk of *Saccharomyces boulardii* is filled in aluminum foil sachet.
The product is presented as a carton of 10 sachets.

• Marketing Authorization Holder and Manufacturing Site Address:

Name of the Company : Bharat Biotech International Limited
Address of the Site & : Genome Valley, Shameerpet Mandal,
Corporate Office Medchal District - 500078, Telangana,
India.

Phone No. : +91-40-2348 0567.

Fax No. : +91-40-2348 0560.

E. Mail : info@bharatbiotech.com

Website : www.bharatbiotech.com

• Marketing Authorization Number(s)

Rwanda FDA-HMP-MA-0049

• Date of First Authorization/ Renewal of the Authorization

Date of first authorization: 17 March 2021

• Date of Revision of the Text