

SUMMARY OF PRODUCT CHARACTERISTICS

Normagut sachets

Saccharomyces boulardii

Saccharomyces boulardii is nonpathogenic, probiotic yeast which nutritionally supports the health of the gastrointestinal tract.

Tutti-Fruity flavor

1. Name of the Medicinal Product:

1.1 Product Name

Normagut sachets

1.2 Strength

Provided in quality and quantitative composition

1.3 Pharmaceutical Dosage Form

Oral powder

2. Quality and Quantitative Composition:

2.1 Qualitative Declaration

2.2 Quantitative Declaration

Each sachet contains:

Dry Yeast of *Saccharomyces boulardii* (*Saccharomyces cerevisiae* (*boulardii*)) 282.5 mg

Equivalent to *Saccharomyces cerevisiae* (*boulardii*) 250 mg

(*Saccharomyces cerevisiae* (*Boulardii*) 2.5 billion organisms)

3. Pharmaceutical Form:

Fruit flavoured free flowing off-white to light brown powder

4. Clinical Particulars:

4.1 Therapeutic indications

- For establishment and maintenance of a well-functioning intestinal flora and an intestinal health.
- Treatment of acute diarrhea by reducing the duration and severity of symptoms.
- Prevention of traveler's diarrhea.
- Prevention of Antibiotic Associated Diarrhea.
- In patient with *H.pylori* infection, along with standard triple therapy for increasing the eradication rates and decreasing overall therapy-related side effects, particularly diarrhea.

4.2 Posology and method of administration

Adults and Children 2 years old and over: 1 sachet once or twice daily

Children less than 2 years: as directed by a physician

Direction of use: Pour the powder in sachet in a little of water or sweetened beverage, mix and drink. The powder can be mixed with food. It should not be poured or mixed with very cold or very hot liquids or food or alcoholic drinks.

4.3 Contraindications

It should not be used with known hypersensitivity to yeast or any component of product. Even though fungemia with *S. boulardii* is infrequent, it may be prudent to closely follow up the adult in patients who are severely ill or in intensive care units and have central catheter for episodes of unexplained fever. Some studies have recommended not giving *S. boulardii* to immunosuppressed patients or those with central catheters to reduce this risk.

4.4 Special warning and precautions for use

Should consult the physician, if diarrhea last longer than 2 days.

4.5 Interaction with other medicinal products and other forms of interaction

Taking Normagut with medications for fungal infections can reduce the effectiveness of Normagut.

4.6 Fertility, pregnancy and lactation

There is no sufficient safety data for the use of *Saccharomyces boulardii* during Pregnancy & Lactation. The use of *Saccharomyces boulardii* during pregnancy & lactation should be avoided.

4.7 Effects on ability to drive and use machine

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

May often cause flatulence

4.9 Overdose and Treatment:

Have not been reported.

5. Pharmacological Properties:

5.1 Pharmacodynamic Properties

Probiotics like *Saccharomyces boulardii* is nonpathogenic microorganisms. It has been suggested that they improve host barrier function, produce competitive inhibition of pathogenic bacteria, and bolster immune function. It also secretes enzymatic proteins, including a protease that degrades *Clostridium difficile* toxins and a phosphatase that inactivates endotoxins such as the lipopolysaccharide produced by *E. coli*.

5.2 Pharmacokinetic Properties

Saccharomyces boulardii is taken orally and eliminated via the stools. Published pharmacokinetic studies show that *Saccharomyces boulardii* has a half-life of 6 hours and that less than 5% (independent on the dose) of viable cells can be recovered in the stools.

Viable *Saccharomyces boulardii* cells achieve a stable level within 3 days and are no longer detectable in the stools than 2 to 5 days after completion of the treatment. A permanent colonization does not take place in human beings.

5.3 Preclinical Safety Data

The preclinical data are incomplete. Due to the long-term medical application, however, there is a sufficient proven safety margin available in human beings.

The results of a mutagenicity study (AMES Test) show that the *Saccharomyces boulardii* does not possess any mutagenic effects in this test system.

Investigations on reproduction toxicity and carcinogenicity are not available.

6. Pharmaceutical Particulars:

6.1 List of excipients

Lactose, Fructose, Silica Colloidal Anhydrous, Tutti-Fruity flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months from manufacturing date.

6.4 Special precautions for storage

Store below 25 °C, dry place and protect from heat and light.

6.5 Nature and contents of container

Powder in sachet, unit carton containing 10 and 30 sachets

Net Weight: 765 mg per sachet

6.6 Special precautions for disposal and other handling

No special requirements.

7. Manufactured by :

MEGA LIFESCIENCES (AUSTRALIA) PTY. LTD.

60, National Avenue, Pakenham, Victoria 3810, Australia

8. Marketing Authorization Holder:

Mega Lifesciences Public Company Limited

Samutprakarn, Thailand

9. Marketing Authorization Numbers:

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10. Date of first authorization / renewal of the authorization:

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11. Date of revision of the text:

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Note:

Read the instructions carefully before use.

Do not use the product after the expiry date.

Do not use the product if there are any significant changes in appearance of the powder.

Keep out of reach of children.