

FLORAMYCES™

DAIRY/LACTOSE-FREE STRAIN OF *SACCHAROMYCES BOULARDII*60 VEGETARIAN CAPSULES | NPN80083479 | FLM060-CN

FloraMyces™ is a special strain of non-GMO *Saccharomyces boulardii* isolated from litchi fruits. Unlike other products containing this organism, FloraMyces™ is dairy and lactose free and does not require refrigeration—it is stable at room temperature for up to 2 years. Benefits of this source may include broader bioactivity and increased protection of the digestive mucosa. Also, it is this strain that has been most studied for its efficiency in the prevention of antibiotic-associated diarrheas, and as a general supplement for optimal gastrointestinal health. Each two-capsule serving contains 10 billion live cells at time of manufacture.

FLORAMYCES™ MAY BE HELPFUL FOR:

- Diarrhea
- Antibiotic-associated diarrhea
- Dysbiosis
- Traveler's diarrhea
- Restoration of optimal GI microflora and mucosal health
- Opportunistic bacterial overgrowth
- Opportunistic yeast overgrowths

UNIQUE MANUFACTURING PROCESS

The *S. boulardii* contained in FloraMyces[™] is obtained through a proprietary patented drying process. Unlike this unique process, *S. boulardii* supplements are typically produced via freeze-drying, which causes a shock to yeast cells and alters their integrity. The very low temperature (freezing) and high vacuum applied:

- Damages the cell walls and consequently the integrity of the cells
- Damages proteins and cell enzymes, leading to cell damage and high cell mortality

Moreover, rehydration of the lyophilisate increases cell mortality depending on the temperature and liquid medium used, causing further damage to and weakening of the cells, with an increase in cell mortality and low viability in gastrointestinal transit.

The patented process used to produce this product's *S. boulardii* is based on less aggressive drying at controlled temperature and lower vacuum, which offers the following benefits:

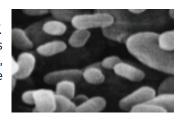
- Eliminates the drawbacks normally associated with freeze-drying
- Preserves whole yeast cells
- Maintains the water content unchanged over time
- Delays consequential aging processes, cell deterioration and contamination of the product to provide greater stability over time

Gut ecology is a complex system based on the equilibrium of different bacterial species. Disturbance of this equilibrium (dysbiosis) by infectious diseases and very often by antibiotic treatments can lead to clinical symptoms of diarrhea. Severe antibiotic associated diarrhea can give rise to *Clostridium difficile* diarrhea, a severe disorder which has a high rate of relapse and is difficult to cure with conventional treatments. The use of probiotics, particularly *Saccharomyces boulardii*, as alternatives to antibiotics, is therefore becoming more attractive.

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BINDING OF ENTEROHAEMORRHAGIC E. COLI

Through its mannose-dominant outer membrane *S. boulardii* has the ability to bind *E. coli* and *Salmonella* – the bacteria responsible for diarrhea, especially traveler's diarrhea. The large cell surface of the yeast allows the binding of many bacterial cells, limiting their capacity to bind to the intestinal epithelium. In this way the bacteria are likely to be eliminated in the stool.



THE HISTORY OF SACCHAROMYCES BOULARDII

Interest in *S. boulardii* began around 1920 when French microbiologist Henri Boulard living in Vietnam noticed that consuming a particular local drink alleviated symptoms of diarrhea in villagers afflicted by an epidemic of cholera. The drink was made from tropical fruits such as litchi and mango. Dr. Boulard isolated an active agent from this drink, which proved to be a live yeast of natural origin which now bears his name, *Saccharomyces boulardii*. Modern science has now elucidated most of the mechanisms of action of *S. boulardii*, such as the inactivation of *C. difficile* toxins, competitive exclusion of pathogens like *E. coli* and various yeasts, specific immune stimulation of the gut, and restoration of functional lactic acid-producing flora.

BIOLOGICAL ACTIVITY

S. boulardii has shown natural resistance to antibiotics, so it can be given to patients receiving antibiotics (Czerucka, 2007). It has been shown to stimulate enzymes of the intestinal brush-border, specifically, sucrase, lactase and maltase (Ibid). The probiotic properties of this organism include: (a) Binding of enterohaemorrhagic E. coli and Salmonella; (b) Protection of the digestive mucosa; (c) Promotion of growth of lactic acid producing bacteria in the gut; (d) Protection against Clostridium difficile toxins; and (e) Stimulating effects on the intestinal mucosa and mucosal immunity. S. boulardii helps preserve tight junctions in the small intestine, decreases inflammatory cytokine production in the gut, and stimulates increased sIgA levels and immune defense in the gut. Additionally, pathogenic bacteria adhere to S. boulardii in the intestinal lumen, resulting in decreased systemic invasion (McFarland, 2010).

In a placebo-controlled study (Surawicz et al.,1989) on patients under antibiotic treatment the results at right were obtained. Although *S. boulardii* does not suppress all antibiotic-associated diarrhea, the fact that it reduces the risk by half is significant (Marteau, 2000). *S. boulardii* may also be helpful for eradication of *H. pylori*. A systematic review and meta-analysis showed that the addition of *S. boulardii* to standard *H. pylori* eradication treatments significantly increased eradication rates and decreased therapy-related side-effects (Szajewska, 2015). Additionally, *S. boulardii* has been shown to improve histology and quality of life in patients with IBS-D when added to standard treatment with ispaghula (psyllium) husk compared to placebo with ispaghula husk (Abbas, 2014), although other studies failed to corroborate this effect. Regarding Crohn's disease, among a small cohort of Crohn's patients in remission, 37.5% of those treated with the NSAID mesalamine for six months experienced a clinical relapse compared to 6.25% of those treated with mesalamine plus *S. boulardii* (Guslandi, 2000). Research supports a potential synergy between *S. boulardii* and mesalamine for IBS-D as well: *S. boulardii* alone did not significantly improve IBS-D symptoms, but given in combination with mesalamine, improvement was greater than with mesalamine alone (Bafutto, 2013).

GENETIC IDENTIFICATION

For many years taxonomists have discussed whether *S. boulardii* was a new species of *Saccharomyces* or a specific strain or variant of *Saccharomyces cerevisiae*. Mitochondrial DNA analysis (Mallié, 2001) and microsatellite typing techniques (Hennequin, 2001) have shown that *S. boulardii* is a unique strain or variant of *S. cerevisiae*, but not a new species of the genus *Saccharomyces*. The proper taxonomic name is therefore *Saccharomyces cerevisiae boulardii* (Mallié, 2001).

For more than a decade Institut Rosell and its mother company, Lallemand, Inc., have developed specific research programs to increase the use of *Saccharomyces boulardii* in both animal and human health. Institut Rosell's *Saccharomyces boulardii* (ATCC74012), contained in FloraMyces™, has been compared by genetic typing to the original type *Saccharomyces cerevisiae var boulardii* (Hansen CBS 5926) and has been shown to be genetically identical.

Medicinal Ingredients (per capsule):

Non-Medicinal Ingredients: Hypromellose, microcrystalline cellulose, magnesium stearate (vegetable source). **Recommended Dose:** Adults: Take 2 capsules per day, or as directed by your health care practitioner. If you are on antifungal(s), take at least 2-3 hours before or after. Dosing recommendations are given for typical use based on an average 150 pound healthy adult. Healthcare practitioners are encouraged to use clinical judgement with case-specific dosing based on intended goals, subject body weight, medical history, and concomitant medication and supplement usage.