Yomogi®

Anti-diarrhoeal drug



Causal therapy of acute diarrhoea

Cost effective therapy

Yomogi® – history and its mechanisms of action

The discovery of the yeast *Saccharomyces boulardii* was made by the French microbiologist Henri Boulard. In the 1920s he became aware the natives in Indochina made tea from macerating fruits (lychees, among them) to stop diarrhoea. He succeeded in isolating the agent responsible for the effective treatment of diarrhoea, a special strain of yeast. Boulard gave his name to this yeast – *S. boulardii*.

S. boulardii is a non-pathogenic eukaryotic microorganism that can grow both under aerobic and anaerobic conditions.

Yomogi® is a probiotic drug containing 250 mg of lyophilized yeast cells, corresponding to 2.5 x 10⁹ viable non-pathogenic cells of the yeast strain Saccharomyces cerevisiae HANSEN CBS 5926 (SYNONYM: *Saccharomyces boulardii*). After oral administration, *S. boulardii* yeasts travel through the digestive tract and exert intraluminal effects but will not colonize in the gastrointestinal tract. Approx. 4-6 days after stopping the administration of Yomogi®, *S.boulardii* yeasts can no longer be detected in the stool.

Antimicrobial effect

In the lumen of the digestive tract Saccharomyces boulardii has antagonistic and antitoxic effects

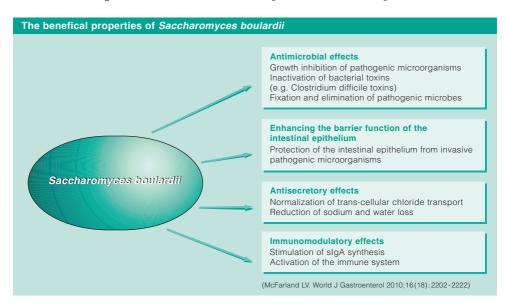
against pathogenic bacteria and yeasts in the intestine. It has been shown that *S. boulardii* secretes a protein/microcin that inhibits the growth of these microorganisms.

Furthermore, *S. boulardii* binds pathogenic bacteria such as Salmonella and specific fimbriae-expressing *Escherichia coli* on their surface. It reduces their adhesion to the intestinal epithelium and eliminates them from the intestine. Bacterial toxins, such as those produced by Clostridium difficile are enzymatically neutralized by *S. boulardii*. The yeast also exerts beneficial effects against various invasive pathogenic bacteria such as Salmonella and Yersinia.

Effect on the intestinal mucosa and immune system

The antisecretory effect of *S. boulardii* normalises the water and electrolyte homeostasis. *S. boulardii* treatment leads to an increase in disaccharidase activity which improves the absorption of carbohydrates.

S. boulardii stimulates the production of secretory immunoglobulin A (sigA) in the gut-associated lymphoid tissue and so helps strengthen the digestive tract defences against infections.

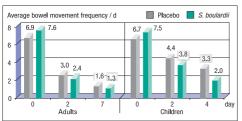


Yomogi® – clinical indications

Acute diarrhoea

Acute diarrhoea is often caused by bacteria or viruses. Apart from the increased frequency of bowel movements and a more liquid stool consistency, fluid and electrolytes are lost to various degrees which can cause life-threatening dehydration.

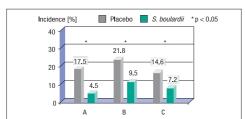
As causal therapy is often impossible, symptomatic treatment becomes important. This includes the normalisation of the water and electrolyte homeostasis. Clinical studies on both children and adults demonstrated the efficacy of the administration of *S. boulardii* for the treatment of acute diarrhoea.



Efficacy of *S. boulardii* in adults (Höchter W et al. Münch med Wschr 1990; 132: 188-192) and children (Cetina-Sauri G et al. Der Kinderarzt 1991; 12:2095-2097) with acute diarrhea

Antibiotic-associated diarrhoea

Antibiotic-associated diarrhoea occurs in about 30% of patients who undergo antibiotic therapy. Patients of advanced age, with compromised immune status or prolonged hospital stays are at higher risk of developing these symptoms. For this indication, S. boulardii has protective and therapeutic effects on the intestinal mucosa. Several clinical studies have demonstrated the yeast reduces the frequency, duration and severity of an antibiotic-associated diarrhoea and helps prevent relapses.



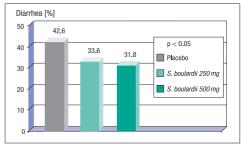
Prevention of antibiotic-associated diarrhea by administration of *S. boulardii* A) Adam J et al. Gazette Medicale de France 1977; 84:2072-2078, B) Surawicz CM et al. Gastroenterology 1989; 96:981-988, C) McFarland L et al. Gastroenterology 1995;90:439-447

Traveller's diarrhoea

Tourists are exposed to higher infectious risk in areas with low hygiene status. Common pathogens in traveller's diarrhoea include enterotoxigenic *E. coli* and Salmonella. The main source of infection is food and water contamination.

Therefore, the first and most effective prophylaxis is good hygiene, e.g. eating only peeled or cooked food and drinking boiled water.

S. boulardii exerts prophylactic therapeutic effects on traveller's diarrhoea as demonstrated in clinical studies.



Antidiarrheal effect of *S. boulardii* on traveler's diarrhea. (Kollaritsch HH et al. Münch med Wschr 1988;38:671-674)

Tips from experience

- During diarrhoeal episodes, take 1 hard capsule of Yomogi[®] 1-2 x per day with liquid before meals
- For prophylaxis of traveller's diarrhoea, start 5 days before departure taking 1 hard capsule of Yomogi[®] 1-2 x per day.
- For administration to children under the age of 6 years, open the hard capsule by separating the two halves and stir into foods or liquids (room temperature).
- To ensure treatment success, therapy with Yomogi® should be continued a few days after the diarrhoea has ceased.
- If microbiological stool analyses are carried out during Yomogi® therapy, the analysing laboratory should be informed of this, so false results are prevented.
- Do not take Yomoqi® together with antimycotic agents.
- Yomogi® can be combined with antibiotics and is therefore ideal for treating antibiotic-associated diarrhoea.

The causal therapy of acute diarrhea – Cost effective medical therapy with the highest quality standards



Anti-diarrhoeal drug

Active substance: 250 mg lyophilized yeast of Saccharomyces cerevisiae HANSEN CBS 5926 (Synonymic: Saccharomyces boulardii)



Yomogi®

Active substance: Saccharomyces cerevisiae HANSEN CBS 5926

Qualitative and quantitative composition: 1 hard capsule YOMOGI contains: 250 mg lyophilized yeast of Saccharomyces cerevisiae HANSEN CBS 5926 (synonym: Saccharomyces boulardii) with at least 2.5x109 viable cells. List of excipients: anhydrous lactose, magnesium stearate, gelatin, water, sodium dodecylsulfate, copper chlorophyllin, titanium dioxide, hydrated ferric oxide. Therapeutic indications: For the relief or treatment of diarrhoea. Helps to reduce occurrence and relieve diarrhoea after antibiotic use. Helps to reduce occurrence and relieve traveller's diarrhoea. May reduce the risk of traveller's diarrhoea. Directions for use: For the relief or treatment of diarrhoea. Adults: 1 capsule 1-2 times daily. Children: 2-6 years of age, same dosage but the hard capsule is to be opened and contents stirred into food or liquid. Travellers' diarrhoea: 1 capsule 1-2 times daily starting 5 days before departure and continue for the duration of travel. If symptoms persist consult your healthcare practitioner. If diarrhoea persists for more than 6 hours in infants under 6 months – 12 hours in children under 3 years – 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years, seek medical advice. Contraindications: YOMOGI is contraindicated in patients, who are hypersensitivie to yeast or any other components of this drug. Paediatric use: No adequate studies are available on the use of this drug in infants and small children. Therefore, it should not be used in children under 2 years of age. Due to the as yet not assessable risk of a systemic colonization with Saccharomyces boulardii, patients with a weakened immune defense system (e.g. HIV infections, organ transplantation, leukaemia, malignant tumors, radiotherapy, chemotherapy, long-term large-dose cortisone treatment) and patients with a central venous catheter should not use this drug without close medical supervision. Precautions relating to use: Pregnancy and lactation: Based on the broad use of yeast as a foodstuff, there are no indications of risk during pregnancy and the lactation period. However, there are no clinical studies on the safety of Saccharomyces cerevisiae during pregnancy. Therefore this medicine should not be used during pregnancy and lactation. Results of experimental studies on Saccharomyces cerevisiae are not available. Undesirable effects: Taking this drug may often cause flatulence. In very rare cases intolerance reactions in the form of pruritus, urticaria, skin rash either localized or over the whole body (generalized exanthema) as well as Quincke's edema, shortness of breath, and allergic shock may occur. If you notice one of the above-mentioned side effects, especially swelling of the mucosa in the facial region (Quincke's edema), shortness of breath, or signs of allergic shock, stop taking this drug and (immediately) inform a doctor so that he/she can decide on the degree of severity and any treatment measures which might be required. Estimates of frequency of these adverse reactions cannot be made. Precautions for handling and storage: This medicinal drug contains lactose. Do not store above 25 °C



Ardeypharm GmbH Loerfeldstr. 20 58313 Herdecke, Germany www.ardeypharm.de Distributed by:



PO Box 7302 West Lakes, South Australia 5022 TEL: 1300 819 765, www.yomogi.com.au