B clausii SC109

Bacillus clausii is an aerobic, spore-forming bacterium that is able to survive transit through the acidic environment of the stomach and colonize the intestine even in the presence of antibiotics. The alkaliphilic nature of the organism has also proved it to be useful in preventing and treating various gastrointestinal disorders as an oral bacteriotherapy. This organism can be found in many alkaline environments, including soil and marine habitat. Similar to other Bacillus species, B. clausii forms endospores, which are resistant to most chemical and physical conditions. B. clausii has also been shown to maintain normal intestinal microflora and improve digestibility.

Due to its spore forming ability, B. clausii has high heat and acid resistance. This characteristic allows spores to survive the harsh manufacturing process and ensures a long-term viability without the need for refrigeration, a property that most non-spore-formers (Lactobacillus sps.) do not possess. Additionally, the spores are capable of surviving the low pH of the gastric barrier which allows the entire dose of ingested bacteria to reach the small intestine intact.

Characteristics of B. clausii SC109

Parameter	**Description**
Organism	B. clausii
Origin	Human intestines
Appearance	Off-white to white free flowing powder
Functional use	Probiotics
Physical characteristics	Spores
Odor	None
Shelf life	24 months

Intended Use:

B. clausii SC109 is a standardized powder intended to be used as a food ingredient and probiotic in select food categories in the amount of $1x10^8$ cfu/serving. The intended uses of *B. clausii* SC109 include addition to bakery (biscuits, pastries, cookies, brownies, crackers), cereal bars, dairy products (yogurt, cottage cheese, hard cheeses, and milk drinks and substitute products) and vegetable and fruit juices. It is recognized that there are Standard of Identity

requirements for some of these specified foods and these foods will not be referred to by their commonly recognized names.

Benefits of Bacillus Clausii

- Modulates the immune system (upregulates T reg system)
- Replenishes microflora during antibiotic therapy
- Supports upper and lower respiratory health
- Effective against “superbugs” like Staphylcoccus aureus, Enterococcus faecium, and Clostridium difficile
- Improves chronic diarrhea

Available Clinical Studies Conducted with B. clausii

Form/ Duration	Study Details and Results	Reference
B. clausii/ 14 days	In this study, 120 patients were recruited and randomly received rabeprazole, clarithromycin and amoxicillin and B. clausii (each preparation containing 2 x 10^9 spores) or placebo for 14 days. Side effects were assessed for 4 weeks from the start of treatment. Diarrhea, nausea, epigastric pain was found to be treated by administration of B. clausii compared to placebo. B. clausii administration did not showed any side effect.	Nista et al. (2004)
B. clausii/ 90 days	Randomized trial in 80 children were enrolled. They were divided into two groups. 40 children received B. clausii (one vial) twice daily for 90 days in group 1 and 40 children were in controlled group allocated in group 2. Examination of children was done every month for 3 months. Diagnosis of respiratory infection was made when at least two symptoms of fever like mucopurulent rhinorrhea, stuffy or dripping nose or both, sore-throat, cough (dry or productive), otalgia (earache), fever, dyspnea, and mucopurulent secretion was present for at least 48 hours. Group 1 reduced the duration of RI (recurrent respiratory infection) compared to group 2 and number of RI was shorter in group 1 than in group 2. It was concluded that B. clausii prevents RI activity in children.	Marseglia et al. (2007)
B. clausii/ 4 weeks	Subjects (n=10) suffering from rhinitis allergy was enrolled. The mean age of the subjects was up to 22.3 years. Subjects suffering from rhinitis allergy were administered with 3 vials per day with B. clausii spores (2 billion spores/vial Enterogermina) for 4 weeks. In all subjects, nasal lavage was performed before and after treatment. Cytokines like IL4, IL10, IFN-gamma and TGF was measured. A decrease in IL4 was seen on treatment with B. clausii and increases in IL10, IFN and TGF were seen.	Ciprandi et al. (2005)
B. clausii/ 1 month	Patients having gastrointestinal symptoms such as bloating, flatulence, abdominal discomfort, abdominal pain and diarrhea underwent a hydrogen glucose breath test (GBT). This study included 40 patients with abnormal	Gabrielli et al. (2009)

	GBT of mean age 30±15 years who were administered with B. clausii ($2X10^9$ spores) 1 vial three times a day for 1 month. Normalization of GBT was 47% and only one patient experienced side effect such as constipation. Treatment with B. clausii was well tolerated and safe to use.	
B. clausii/ 5 days	Children (n=136) were hospitalized (aged 6 months to 5 years) to evaluate effectiveness of B. clausii in reduction of acute diarrhea. Children were divided into two groups: a treatment group (n=90) that received B. clausii (2 x 109 CFU/5 ml) and a placebo group that received a placebo for 5 days. Duration of diarrhea, frequency of diarrhea and duration of hospital stay was recorded. The number of stools was decreased on day 3 and day 4 of treatment.	Maugo (2012)
B. clausii/ 10 days	Twenty seven patients aged 35.44±8.08 years were included who had loose motions within 24 hours for more than 7 days. Diarrhea, frequency of defecation, abdominal pain and stool frequency was tested on 1, 3, 6 and 10 day. They were given one capsule of B. clausii strain UBBC-07 (2 x 109 cfu) twice a day for 10 days. Duration of diarrhea, frequency of defecation, abdominal pain decreased and stool consistency improved.	Sudha et al. (2013)
B. clausii/ 7 to 21 days	A multi-centric, open-labeled clinical trial was conducted in 223 infants and children aged 6 months to 12 years suffering from antibiotic associated diarrhea. They were divided in two groups. The treatment group (n=162) received 1 vial of 2 x 10^9 of B. clausii spores per “orem” within 24 hours. The placebo group received (n=61) the placebo. Children already suffered from respiratory, genitourinary or skin and soft tissue infection therefore undergoing antibiotic treatment for approximately 8 days. A lower incidence of diarrhea was observed in the B. clausii treated group.	Destura (2013)
B. clausii/ 12 days	Randomized, open-labeled, cross -over trial was conducted for 12 days by oral administration of a commercial probiotic formulation containing B. clausii strains (OC, NR, SIN, T). B. clausii in feces was counted on selective media. In feces, B. clausii was found alive up to 12 days. The amount of recovery of OC, NR, SIN, T was higher than spores administered in some volunteers. B. clausii strains can germinate, multiply and survive in intestinal environment.	Ghelardi et al. (2015)
B. clausii/ 5 days	The study was conducted in 131 hospitalized children aged 6 month to 12 years and divided into two groups. Group 1 comprised children administered with an oral rehydration therapy (ORT) with zinc and B. clausii and group 2 was treated with ORT and zinc. Children received one mini bottle containing 2 billion spores of B. clausii per day for 5 days. Follow up was done at 6, 12, 24, 36, 48, 60 and 72 hours. Duration of diarrhea, frequency of diarrhea, duration of hospital stay, direct and indirect costs parameters were studied. Duration and frequency of diarrhea and hospital stay was found to be reduced thereby downscaling the financial burden.	Keya et al. (2015)
B. clausii/ 10 days	Twenty seven patients (aged 35.44±8.08 years) who had ≥ 3 loose motions in 24 hours for more than 7 days. All patients were administered with B. clausii strain UBBC-07 (containing 2 x 109 cfu) twice a day for 10 days.	Jayanti et al. (2015)

	Duration of diarrhea, frequency of defecation, abdominal pain and stool frequency was seen on day 1, 3, 6 and 10. Duration of diarrhea, frequency of defecation, abdominal pain was decreased. Stool consistency was found to be improved from watery to soft. No change in safety parameters were observed.	