

# Ortho Spore Complete



## CLINICAL APPLICATIONS

- Helps Gently Restore and Maintain Microbial Balance and Diversity
- Reduces Gas, Bloating, and Food Intolerance
- Improves Occasional Constipation and Diarrhea
- Maintains GI Barrier Integrity

## GASTROINTESTINAL SUPPORT



Ortho Spore Complete is a unique spore-based, broad-spectrum probiotic formula designed to promote a healthy gut microbiota, support gastrointestinal (GI) health, and support immune function. Ortho Spore Complete is specifically formulated with several spore-based probiotic strains to promote diversity and balance within the host gut microbiota. Each capsule provides key *Bacillus* strains that remain in a dormant, protective state in the harsh GI environment, then become active on target to transiently re-establish and recondition the gut.

### Overview

A healthy GI tract is a finely balanced environment where countless microbes compete for space and nutrients.<sup>1</sup> Under conditions of health, the ecosystem is balanced (eubiosis), and few GI and extra-intestinal symptoms exist. However, dysbiosis can occur when an overabundance of potentially harmful organisms prevails. Therefore, the health of the GI tract relies on balanced microbiota. Probiotics contribute to balance by positively influencing the intestinal environment via pH balance, microorganism diversity, and immune signaling. The natural microbiota balance can be upset by numerous lifestyle factors such as medications, excessive alcohol consumption, low stomach acid, or poor diet.

Probiotics have been extensively studied and characterized by having broad GI and immune benefits. These include supporting the population of healthy commensal microbes following microbiota imbalance; supporting healthy bowel function; increasing the production of short-chain fatty acids, which provide energy to the cells of the intestinal lining; strengthening the gut-immune barrier by promoting

a healthy gut mucosa; enhancing detoxification of harmful compounds; and aiding in the digestion of compounds like lactose and casein.

Probiotics are live organisms and must be shelf-stable through the expiration date, so they can be precisely delivered to the intestinal tract and have maximum benefit. *Bacillus* spores transition between a dormant and an active, vegetative form, depending on the environment. *Bacillus* spores remain dormant in harsh environments until they reach more favorable environments like the human GI tract. In its dormant spore form, *Bacillus* surrounds itself with an endospore. The endospore is a tough, natural outer shell that protects it from light, heat, pressure, acid, lack of oxygen, and other environmental factors. The *Bacillus* spore transitions to its active, vegetative form in the large intestine. The vegetative form can then transiently colonize the gut. In its active form, *Bacillus* probiotics can increase microbial diversity by changing the local pH and increasing the production of short-chain fatty acids. The combination of specific *Bacillus* probiotic species, particularly *Bacillus coagulans*, *Bacillus clausii*, and *Bacillus subtilis*, relieve symptoms for common GI complaints and reinforce healthy gut function.<sup>2</sup>

### ***Bacillus coagulans* (strains MTCC 5856 [LactoSpore®] and SNZ 1969)**

*Bacillus coagulans* supports a balanced microbiota by having antagonistic effects against unwanted organisms and supporting healthy commensal microbes. In an *in vitro* mechanism study, *B. coagulans* demonstrated antagonistic action against a variety of undesirable organisms.<sup>3</sup> *B. coagulans* supplementation at a dose of 1 billion CFU/day for 28 days

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in adults over age 65 increased fecal concentrations of the commensal *F. prausnitzii* from baseline compared to placebo; fecal *Bacillus* spp. also increased in this population.<sup>4</sup>

*B. coagulans* supports GI health. *B. coagulans* MTCC 5856 given at a dose of 2 billion CFU/day reduced symptoms related to occasional diarrhea in adults with GI disturbance after 90 days of supplementation.<sup>5</sup> Another study found *B. coagulans* MTCC 5856 was safe when given at the 2 billion CFU dose for 30 days in a group of healthy subjects.<sup>6</sup> Symptoms of occasional GI discomfort significantly improved with supplementation of a combination of *Bacillus* probiotic strains at total dose of 2 billion CFU/day (i.e., *B. coagulans* SNZ 1969, *B. clausii* SNZ 1971 and *B. subtilis* SNZ 1972) for 30 days in 60 adults with occasional GI discomfort.<sup>2</sup>

### **Bacillus clausii B106**

*Bacillus clausii* supports GI health, a balanced intestinal microbiota, and immune health. *B. clausii* at a dose of 2 billion CFU twice per day for 10 days has demonstrated significant effectiveness in adults with occasional diarrhea.<sup>7</sup> *B. clausii* has significantly reduced the duration of occasional diarrhea and decreased stool frequency in a meta-analysis of 1,298 children with dosages ranging from 1 billion CFU twice per day to 4 billion CFU/day.<sup>8</sup> *B. clausii* has also shown benefit as a probiotic in subjects with small intestinal bacterial overgrowth via normalization of glucose breath test when given at a dose of 2 billion CFU, three times per day for one month in an open-label study.<sup>9</sup> *B. clausii* at an oral dose of 2 billion CFU twice per day was shown to maintain healthy respiratory function after 90 days in a study of 80 participants.<sup>10</sup>

A recent candidate genome analysis performed on the *B. clausii* B106 strain found genes for several beneficial probiotic properties of the strain (i.e., genes responsible for GI survival and adaptation, adhesion, vitamin synthesis [i.e., riboflavin, folate, biotin], bacteriocins production, stress resistance, etc.).<sup>11</sup> Genes were also present for sporulation, suggesting that *B. clausii* B106 is a resilient and stable probiotic strain.

### **Bacillus subtilis (strains HU58 and HS43)**

*Bacillus subtilis* has been shown to relieve GI distress in patients. *B. subtilis* supplementation of 1-3 billion CFU alongside motility stimulating agents was effective for GI symptom relief at four weeks.<sup>12</sup> Supplementation with *B. subtilis* HU58 plus *B. coagulans* SC208 at a total dose of 3 billion CFU/day significantly improved stool consistency and GI symptoms (i.e., occasional abdominal pain, bloating, flatulence) in patients with occasional diarrhea compared to placebo.<sup>13</sup>

### **Directions**

2 capsules per day or as recommended by your health care professional.

### **Does Not Contain**

Wheat, gluten, soy, corn, animal or dairy products, fish, shellfish, peanuts, tree nuts, egg, artificial colors, artificial sweeteners or preservatives.

### **Cautions**

If you are pregnant or nursing, consult your physician before taking this product.

## **Supplement Facts**

Serving Size 2 Capsules  
Servings Per Container 30

	Amount Per Serving	% Daily Value
<i>Bacillus clausii</i> (B106)	13 mg (1 Billion CFU++)	*
<i>Bacillus coagulans</i> (MTCC5856) (LactoSpore®)	13 mg (1 Billion CFU++)	*
<i>Bacillus coagulans</i> (SNZ1969)	13 mg (1 Billion CFU++)	*
<i>Bacillus subtilis</i> (HU58)	13 mg (1 Billion CFU++)	*
<i>Bacillus subtilis</i> (HS43)	6.5 mg (1 Billion CFU++)	*

\* Daily Value not established.

**ID# 477060 60 Capsules**

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**eFFICACY**  
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## References

1. Gilbert JA, Blaser MJ, Caporaso JG, Jansson JK, Lynch SV, Knight R. Current understanding of the human microbiome. *Nat Med.* 2018;24(4):392-400.
2. Soman RJ, Swamy MV. A prospective, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of SNZ TriBac, a three-strain *Bacillus* probiotic blend for undiagnosed gastrointestinal discomfort. *Int J Colorectal Dis.* 2019;34(11):1971-1978.
3. Shukla P, Sharma J. A Study showing antagonistic effect of *Lactobacilli casei* and *Lactobacilli* sporogenesis against some common pathogens- in vitro. 2015.
4. Nyangale EP, Farmer S, Cash HA, Keller D, Chernoff D, Gibson GR. *Bacillus coagulans* GBI-30, 6086 Modulates *Faecalibacterium prausnitzii* in Older Men and Women. *J Nutr.* 2015;145(7):1446-1452.
5. Majeed M, Nagabhushanam K, Natarajan S, et al. *Bacillus coagulans* MTCC 5856 supplementation in the management of diarrhea predominant Irritable Bowel Syndrome: a double blind randomized placebo controlled pilot clinical study. *Nutr J.* 2016;15:21.
6. Majeed M, Nagabhushanam K, Natarajan S, et al. A Double-Blind, Placebo-Controlled, Parallel Study Evaluating the Safety of *Bacillus coagulans* MTCC 5856 in Healthy Individuals. *Journal of Clinical Toxicology.* 2016;6:283.
7. Sudha MR, Bhonagiri S, Kumar MA. Efficacy of *Bacillus clausii* strain UBBC-07 in the treatment of patients suffering from acute diarrhoea. *Beneficial microbes.* 2013;4(2):211-216.
8. Ianiro G, Rizzatti G, Plomer M, et al. *Bacillus clausii* for the Treatment of Acute Diarrhea in Children: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Nutrients.* 2018;10(8).
9. Gabrielli M, Lauritano EC, Scarpellini E, et al. *Bacillus clausii* as a treatment of small intestinal bacterial overgrowth. *Am J Gastroenterol.* 2009;104(5):1327-1328.
10. Marseglia GL, Tosca M, Cirillo I, et al. Efficacy of *Bacillus clausii* spores in the prevention of recurrent respiratory infections in children: a pilot study. *Ther Clin Risk Manag.* 2007;3(1):13-17.
11. Kapse NG, Engineer A, Vasudevan G, Wagh S, Dhakephalkar P. Genome Profiling for Health Promoting and Disease Preventing Traits Unraveled Probiotic Potential of *Bacillus clausii* B106. *Microbiology and Biotechnology Letters.* 2018;46:334-345.
12. Choi CH, Kwon JG, Kim SK, et al. Efficacy of combination therapy with probiotics and mosapride in patients with IBS without diarrhea: a randomized, double-blind, placebo-controlled, multicenter, phase II trial. *Neurogastroenterol Motil.* 2015;27(5):705-716.
13. Mehta DS, DeSouza A, Jadhav SS, Devale M. An open labeled, placebo controlled trial to evaluate the role of probiotics- *Bacillus subtilis* HU58 and *Bacillus coagulans* SC208 on antibiotic associated diarrhea in humans. *Biomedical Journal of Scientific & Technical Research.* 2020;29(4):22679-22684.