

ORTHO SPORE IG®



CLINICAL APPLICATIONS

- *Helps Maintain Normal Gastrointestinal Balance*
- *Provides Concentrated Immunoglobulins to Enhance Mucosal Immunity*
- *Supports Digestion and Micronutrient Absorption*
- *Maintains GI Barrier Health and Integrity*



GASTROINTESTINAL SUPPORT

Ortho Spore IG® is a spore-based, broad-spectrum probiotic formula designed to promote a healthy gut microflora, protect mucosal integrity, and relieve small intestinal bacterial overgrowth (SIBO). Each capsule provides key *Bacillus* spore-forming probiotic strains that remain in a dormant protective state in the harsh gastrointestinal environment yet become active on target to colonize and recondition the gut. Uniquely included in this formula are serum-derived bovine immunoglobulins that bind to microbes and toxins that are common in SIBO.

Overview

SIBO is a condition that occurs when there is an overabundance of commensal bacteria from the colon present in the small intestine. SIBO is largely overlooked and more prevalent than previously thought.¹ The health of the small intestines relies on balanced microbiota, and probiotics and immunoglobulins can contribute to that balance by having a positive influence on the intestinal environment, including pH, organism diversity, and immune signaling. SIBO remains an area of research, but it is understood that dysbiosis and motility are key components. Such dysbiosis of the small intestine can be attributable to low stomach acid, medications, or alcohol consumption.²

Probiotics have been extensively studied and are characterized as having broad gastrointestinal (GI) and immune benefits, including increasing the population of healthy bacteria following microflora 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; aiding in the digestion

of compounds like lactose and casein; and enhancing detoxification of harmful compounds.

Probiotics are live organisms and must be shelf stable through the expiration date, so they can be precisely delivered to the intestinal tract to have maximum benefit. *Bacillus* spores can transition between a dormant and an active form, depending on the environment. *Bacillus* spores remain dormant in harsh environments until they reach more favorable environments like the human gastrointestinal tract. In its dormant spore form, *Bacillus* surrounds itself with an endospore, which is a tough, natural outer shell that protects it from light, heat, pressure, acid, lack of oxygen, and other environmental factors. *Bacillus* changes into its active form in the large intestine to colonize the gut to encourage microbial diversity of commensal gut bacteria. In its active form, *Bacillus* can increase microbial diversity by changing the pH, and increasing the production of short-chain fatty acids. The combination of specific strains, particularly *Bacillus coagulans*, *Bacillus clausii*, and *Bacillus subtilis*, relieve symptoms for common GI complaints and reinforce healthy gut function.³

The discovery that the gut barrier plays a key role in immune health fueled the search to strengthen it. Research has shown that the binding capabilities of immunoglobulins have a positive effect on gut barrier function.⁴ In the search for innovative ways to improve microbiome diversity, we have combined our blend of spore-forming probiotics alongside immunoglobulins uniquely shown to bind to bacteria and toxins, driving immune response. IgG helps to maintain a healthy intestinal immune system by binding a broad range of microbes and toxins within the gut lumen. As these unwanted triggers are removed, it resets healthy immune tolerance and

† These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

builds a stronger barrier to the external environment in the gut. Serum-derived bovine immunoglobulins have the highest IgG concentration available for GI and immune challenges where allergens are a significant concern.

Bacillus coagulans

B. coagulans has been shown to increase the commensal GI microbiota. Supplementation of 1 billion CFU daily for 28 days with *B. coagulans* significantly increased levels of the commensal microbe *F. prausnitzii* from baseline compared to placebo, as well as increased *Bacillus* spp. in fecal samples of adults over 65.⁵ *B. coagulans* has also been shown to relieve GI discomfort and improve stool consistency. *B. coagulans* given once a day for eight weeks showed reduced daily bowel movements and GI symptoms.⁶ *B. coagulans* also significantly improved bowel movements in healthy adults with occasional constipation, as well as decreased abdominal discomfort.⁷

Bacillus clausii

B. clausii is commonly used as a probiotic to promote balance in the microbiome and has showed promising results in individuals with SIBO specifically.⁸ *B. clausii* has demonstrated significant effectiveness in adults with acute diarrhea.⁹ *B. clausii* has also shown to significantly reduce duration of occasional diarrhea and decreased stool frequency in children.¹⁰

Bacillus subtilis

B. subtilis has been shown to relieve GI distress in patients. *B. subtilis* supplementation of 1-3 billion CFU alongside motility stimulating agents was shown effective for relief of GI symptoms at four weeks.¹¹

Serum-Derived Bovine Immunoglobulins

Probiotics are a natural choice for supporting beneficial bacteria in the gut, but supplementation to eliminate unwanted microbes should also be considered. Within the gut barrier, researchers found that the binding capabilities of immunoglobulins have a positive effect on gut barrier function in vitro.⁴ Broad-spectrum binding capabilities (See Table 1) demonstrate the positive influence of serum-derived bovine immunoglobulins.⁴ This binding and elimination decreases microbe and toxin encounters by the immune system and resets immune tolerance.^{12,13}

Table 1: Serum-Derived Bovine Immunoglobulin Binding Capacity

Bacterial Component	Description
Lipopolysaccharide (LPS)	Bacterial cell wall component
C. difficile Toxin A and B	C. diff virulence factors
Peptidoglycan	Bacterial cell wall component
Flagellin	Antigenic bacterial component
Zymosan	Fungal cell wall component
c-di-AMP	Bacterial messenger molecule
CpG	Bacterial DNA motif
Pam3CSK4	Bacterial lipoprotein
MDP	Bacterial cell wall component

Directions

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

Does Not Contain

Gluten, artificial colors or flavors.

Cautions

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

Supplement Facts ^{V1}		
Serving Size 3 Capsules Servings Per Container 30		
	Amount Per Serving	%Daily Value
Calories	5	
Total Carbohydrate	<1 g	<1%*
Protein	1 g	
Sodium	5 mg	<1%
Serum-Derived Bovine Immunoglobulin Protein Isolate (ImmunoLin®)	1 g	**
Immunoglobulin G (IgG)	480 mg	**
Bacillus coagulans (MTCC5856) (LactoSpore®)	12 mg (2 Billion CFU++)	**
Bacillus clausii (CSI08)	3 mg (1 Billion CFU++)	**
Bacillus subtilis (DE111®)	3 mg (1 Billion CFU++)	**
* Percent Daily Values are based on a 2,000 calorie diet. ** Daily Value not established.		

Other Ingredients: Hypromellose (Vegetable Capsules), Rice Maltodextrin and Medium Chain Triglycerides.
++Colony Forming Units

ID# 476090 90 Capsules

References

1. Dukowicz AC, Lacy BE, Levine GM. Small intestinal bacterial overgrowth: a comprehensive review. *Gastroenterol Hepatol (N Y)*. 2007 Feb;3(2):112-22. PMID: 21960820; PMCID: PMC3099351.
2. Bures J, Cyrany J, Kohoutova D, Förstl M, Rejchrt S, Kvetina J, Vorisek V, Kopacova M. Small intestinal bacterial overgrowth syndrome. *World J Gastroenterol*. 2010 Jun 28;16(24):2978-90. doi: 10.3748/wjg.v16.i24.2978. PMID: 20572300; PMCID: PMC2890937.
3. 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. doi:10.1007/s00384-019-03416-w
4. Detzel CJ, Horgan A, Henderson AL, et al. Bovine immunoglobulin/protein isolate binds pro-inflammatory bacterial compounds and prevents immune activation in an intestinal co-culture model. *PLoS One*. 2015;10(4):e0120278. Published 2015 Apr 1. doi:10.1371/journal.pone.0120278
5. 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. doi:10.3945/jn.114.199802
6. Dolin BJ. Effects of a proprietary *Bacillus coagulans* preparation on symptoms of diarrhea-predominant irritable bowel syndrome. *Methods Find Exp Clin Pharmacol*. 2009;31(10):655-659. doi:10.1358/mf.2009.31.10.1441078
7. Madempudi RS, Neelamraju J, Ahire JJ, Gupta SK, Shukla VK. *Bacillus coagulans* Unique IS2 in Constipation: A Double-Blind, Placebo-Controlled Study. *Probiotics Antimicrob Proteins*. 2020;12(2):335-342. doi:10.1007/s12602-019-09542-9
8. Gabrielli M, Lauritano EC, Scarpellini E, Lupascu A, Ojetti V, Gasbarrini G, Silveri NG, Gasbarrini A. *Bacillus clausii* as a treatment of small intestinal bacterial overgrowth. *Am J Gastroenterol*. 2009 May;104(5):1327-8. doi: 10.1038/ajg.2009.91. Epub 2009 Apr 7. PMID: 19352343.
9. Sudha MR, Bhonagiri S, Kumar MA. Efficacy of *Bacillus clausii* strain UBBC-07 in the treatment of patients suffering from acute diarrhoea. *Benef Microbes*. 2013 Jun 1;4(2):211-6. doi: 10.3920/BM2012.0034. PMID: 23443952.
10. 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):1074. Published 2018 Aug 12. doi:10.3390/nu10081074
11. 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 [published correction appears in *Neurogastroenterol Motil*. 2015 Nov;27(11):1684-5. Dosage error in article text]. *Neurogastroenterol Motil*. 2015;27(5):705-716. doi:10.1111/nmo.12544
12. Jasion VS, Burnett BP. Survival and digestibility of orally-administered immunoglobulin preparations containing IgG through the gastrointestinal tract in humans. *Nutr J*. 2015;14:22. Published 2015 Mar 7. doi:10.1186/s12937-015-0010-7
13. Petschow BW, Burnett B, Shaw AL, Weaver EM, Klein GL. Serum-derived bovine immunoglobulin/protein isolate: postulated mechanism of action for management of enteropathy. *Clin Exp Gastroenterol*. 2014;7:181-190. Published 2014 May 24. doi:10.2147/CEG.S62823