INGREDIENTS

*Bacillus coagulans* is a non-pathogenic, non-toxic, spore forming microorganism. *Bacillus coagulans* was originally known as *Lactobacillus sporogenes* which is now considered an outdated name. It's scientifically correct name is *Bacillus coagulans*. Even though it produces lactic acid, it is not considered a *Lactobacillus*. When ingested, spores of *Bacillus coagulans* are able to tolerate the acidic environment of the stomach allowing the spores to germinate and proliferate within the GI tract. After germination, *Bacillus coagulans* starts producing lactic acid in the intestine. The production of lactic acid prevents the growth of pathogenic microbes (bad bacteria) and allows *Bacillus coagulans* (good bacteria) to dominate the microflora.

LactoSpore® is the spore form of *Bacillus coagulans*. LactoSpore® is resistant to most chemical and physical conditions (e.g. acid & heat) allowing it to survive shipping and storage without refrigeration.

BENEFITS

- LactoSpore® is a patented, room temperature-stable probiotic
- LactoSpore® is capable of surviving the acidic environment of the stomach
- LactoSpore® helps support:
  - Healthy digestion
  - Management of diarrhea in: *Irritable Bowel Syndrome*, *Antibiotic-associated diarrhea*, *Infants*
  - Dental health
  - Healthy cholesterol markers
  - Healthy metabolic markers
  - Healthy blood lipid and antioxidant markers

CLINICAL STUDIES

A double-blind, placebo-controlled, multi-centered trial evaluated the safety and efficacy of *B. coagulans* MTCC 5856 in diarrhea-predominant Irritable Bowel Syndrome (IBS) patients. Thirty six newly-diagnosed diarrhea-predominant IBS patients were enrolled in three clinics. Along with standard care, 18 patients received placebo, while 18 patients received *B. coagulans* MTCC 5856 tablets for 90 days. Clinical IBS symptoms were primary measures, evaluated through questionnaires. Physician’s global assessment and IBS quality of life were secondary measures, monitored through questionnaires.

There was a significant decrease in clinical symptoms like bloating, vomiting, diarrhea, abdominal pain and stool frequency in patient group receiving *B. coagulans* MTCC 5856 compared to placebo group. Similarly, disease severity also decreased and quality of life increased in group receiving *B. coagulans* MTCC 5856. *B. coagulans* MTCC 5856 was deemed safe and effective in diarrhea-predominant IBS patients for 90 days of supplementation. The study concluded that *B. coagulans* MTCC 5856 could be a potential agent in the management of diarrhea-predominant IBS patients.

A related study evaluated effects of adding a probiotic to mineral oil for treatment of functional constipation in children. This controlled trial was conducted on 60 children (2 to 14 yr old) with functional constipation. Children received *B. coagulans* (*Lactobacillus sporogenes*) plus mineral oil (paraffin) or mineral oil alone for two months. Constipation symptoms were assessed and compared before and after intervention. After treatment, the two groups were also compared regarding subjective global assessment of improvement. The researchers concluded that adding *B. coagulans* (*Lactobacillus sporogenes*) to mineral oil can increase improvement in constipation symptoms of children without specific side-effects.

A similar study evaluated the efficacy and safety of a medical device containing a combination of Simethicone and *Bacillus coagulans* (Colinox®) in treatment of Irritable Bowel Syndrome (IBS). The study was a monocentric, double-blind, placebo-controlled, parallel group clinical trial. Adult subjects experiencing IBS, as defined by Rome III criteria, were enrolled. Bloating, discomfort and abdominal pain were assessed as primary end points. Subjects received treatment or placebo 3 times/day after each meal for 4 wks. Subjects were examined at Day 0 (T1), at

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Days 14 (T2) and 29 (T3). Fifty-two patients were included in the study. Intragroup analysis showed a significant reduction of bloating, discomfort and pain in Colin® group (CG) compared to placebo group (PG). Between group analysis confirmed, at T1-T3, significant differences between CG and PG in bloating and discomfort. The researchers concluded that this study demonstrates the efficacy and safety of a combination of simethicone and Bacillus coagulans in treatment of IBS 3.

Other researchers attempted to determine the efficacy of a fructo-oligosaccharides (FOS)-B. coagulans (Lactobacillus sporogenes) preparation in the prevention of diarrhea due to antibiotics in childhood. A multi-center, randomized, double-blind versus placebo study was carried out. A total of 120 children, with active infections requiring antibiotics, were enrolled in the study and treated for 10 days either in experimental group (F) or placebo (P). Study results were recorded from patients’ diaries and follow-up clinical examinations. Out of 98 evaluable patients, 71% in group F had no diarrhea versus 38% in group P. The duration of diarrhea in F and P groups was 0.7 vs 1.6 days, respectively. The researchers concluded that prophylaxis with B. coagulans (Lactobacillus sporogenes), associated to FOS, significantly reduced the number of days and duration of events in children with antibiotic-induced diarrhea 4.

A related study included one hundred and twelve newborn infants, randomized to receive a daily oral dose of 100 million B. coagulans (Lactobacillus sporogenes) or a placebo for one year. Morbidity was monitored each week for 12 months. Ninety four (84%) experienced diarrhea due to rotavirus infection. The group fed B. coagulans (L sporogenes) had fewer episodes of diarrhea, fewer days of illness and episodes of diarrhea were shorter. The number of infants who presented with mild to moderate dehydrartion was 11 in the treated group and 15 in the placebo group, though the difference was not statistically significant. There was a trend for body weight at one year to be higher in the treated group compared with controls, but the difference was not statistically significant. The study concluded that prophylactic feeding of Lactobacillus has a preventive effect on the incidence and duration of acute rotavirus diarrhea 5.

Another study evaluated the effect of probiotics on salivary Streptococcus mutans (SM) counts in children and their anti-caries potential. A placebo-controlled study was undertaken with 150 children (age 7-14 yr). Subjects were randomly divided into three groups (each comprising 50 children): group A - placebo, Group B - combination of B. coagulans (Lactobacillus rhamnosus) and Bifidobacterium, Group C - Bacillus coagulans. Subjects were instructed to mix preparation in 20 ml of water, swish and swallow, for 14 days. Mutans streptococci counts were performed on day one and after 14 days. The study found significantly-reduced salivary Streptococcus mutans (SM) counts in the Bacillus coagulans group after 14 days of probiotic ingestion, suggesting potential dental health benefit 6.

Another study examined short-term hypolipidemic effects of oral B. coagulans (Lactobacillus sporogenes) (360 million spores/day) in 17 patients (mean age 45.6 yr: males 15, females 2) with type II hyperlipidemia in a fixed-dose trial. Over a period of 3 months, significant reductions were observed in total cholesterol and LDL-cholesterol. HDL-cholesterol was marginally increased. There was no change in serum triglyceride concentration. Total cholesterol/HDL cholesterol and LDL cholesterol/HDL cholesterol ratios were significantly reduced after treatment. No adverse effect was noted. The researchers concluded that oral B. coagulans (Lactobacillus sporogenes) therapy may prove to be an important hypolipidemic therapy after confirmation in larger trials 7.

Other researchers investigated effects of synbiotic food consumption on metabolic profiles, C-reactive protein (hs-CRP) and biomarkers of oxidative stress in diabetic patients. The randomized double-blind cross-over controlled clinical trial was performed among 62 diabetic patients aged 35-70 yr. Subjects were randomly assigned to consume either a synbiotic (n = 62) or control food (n = 62) for 6 weeks. A 3-week washout period was applied following which subjects were crossed over to the alternate treatment arm for an additional 6 weeks. The synbiotic food consisted of a probiotic viable and heat-resistant B. coagulans (Lactobacillus sporogenes) with inulin as prebiotic. Patients were asked to consume synbiotic or control food three times a day. Fasting blood samples were taken at baseline and after a 6-wk intervention to measure metabolic profiles, hs-CRP and biomarkers of oxidative stress. Researchers concluded that consumption of a synbiotic food for 6 weeks among diabetic patients had significant effects on serum insulin, hs-CRP, uric acid and plasma total GSH levels 8.

A similar study attempted to determine the effects of synbiotic food consumption on glycemic status and serum high sensitivity C-reactive protein (hs-CRP) levels of pregnant women. The randomized placebo-controlled clinical trial included 52 pregnant women age 18-35 yr, in their third trimester. Subjects were randomly assigned to consume either a synbiotic (n=26) or control food (n=26) for 9 weeks. The synbiotic food consisted of a probiotic B. coagulans (Lactobacillus sporogenes) and inulin as prebiotic. Control food (same substance without probiotic bacteria or inulin) was packed in identical packages. Patients were asked to consume synbiotic and control foods twice a day. Fasting blood samples were taken at baseline and after 9-wk intervention. Consumption of synbiotic food resulted in a significant decrease in serum insulin levels and HOMA-IR (Homeostatic Model Assessment of Insulin), a significant difference in HOMA-B and a significant rise in QUICKI score. The study concluded that consumption of a synbiotic food with B. coagulans for 9 weeks by pregnant women had beneficial effects on insulin actions compared to control food 9.

Another study evaluated the effects of daily consumption of a synbiotic food on blood lipid profiles and biomarkers of oxidative stress in pregnant women. A randomized, double-blind, controlled clinical trial was per-formed among 52 primigravida pregnant women, aged 18-35 yr at their third trimester. Subjects were randomly assigned to consume either a synbiotic (n=26) or control food (n=26) for 9 weeks. The synbiotic food consisted of a probiotic viable and heat-resistant Lactobacillus sporogenes with inulin prebiotic. Patients were asked to consume the synbiotic and control foods two times a day. Biochemical measurements including blood lipid profiles, plasma total antioxidant capacity (TAC) and total glutathione (GSH) were conducted before and after 9 weeks of intervention. The study concluded that consumption of a synbiotic food for 9 weeks resulted in a significant reduction in serum triacylglycerols (TAG) and very low density lipoproteins (VLDL), and a significant rise in plasma GSH levels compared to control food 10.

SAFETY
Generally Recognized As Safe (GRAS)

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