UltraPlex Probiotic IgY

Clinical Applications

- Supports a Healthy Balance of Microflora to Promote Digestive Health*
- Provides Immunoglobulins and Immunoregulating Factors to Promote Systemic Health*
- Enhances the Integrity of Intestinal Mucosa*

UltraPlex Probiotic IgY *features clinically validated ingredients to support microbiome wellness and overall immune health. LactoSpore® (Bacillus coagulans MTCC5856) is a unique strain of shelf-stable L (+) lactic acid-producing bacteria with a naturally protective spore coating. In addition to its research-supported role in promoting healthy bacterial balance in the gut, this strain has been studied for its effects on maintaining blood lipid levels already within a healthy range and its effect on vaginal health. UltraPlex Probiotic IgY (IgY Max™), hyperimmunized egg powder, provides immunoglobulins and immune cofactors to support the body's natural defenses by limiting non-beneficial microbial adhesion.**

All Elevation Ultraplex Formulas Meet or Exceed cGMP Quality Standards

Discussion

Diversity of gut microflora is characteristic of a healthy GI microbiome and contributes to overall health and vitality by promoting optimum digestion, assimilation, gut integrity, motility, and efficient removal of toxins and waste. Many internal and external influences, including stress, a poor diet, food sensitivities, medication, environmental factors, and certain disease conditions, can impact the microbial balance within this fine-tuned community. Their impact can allow for potential colonization by pathogenic organisms and disrupt a healthy balance, which can result in adverse effects ranging from GI symptoms to impaired immune response.[1-3] Probiotics are part of the key to promoting the optimal balance of the microbiome,[4] whether they originate from dietary sources or from supplements. Providing an increased supply of immunoglobulins also encourages a healthy balance of bacteria in the intestine. Due to the link between gut health and systemic health, supporting immunity through enhancement of a healthy GI microbiome balance promotes overall health.*

LactoSpore® *(Bacillus coagulans MTCC5856)*

Lactic acid-producing bacteria are suggested to play a role in GI microecology. They prevent the growth of non-beneficial microorganisms through competitive inhibition, generation of non-conducive acidic environments, and production of antibiotic-like substances.[5] *B coagulans* is a unique lactic acid-producing probiotic strain featuring a thermostable spore coating that enables viability throughout shelf life and the ability to survive gastric secretions intact until reaching the gut.[6] *B coagulans* has a well-documented safety profile.[7] It received premarket safety approval in Canada in 2014 and has USFDA GRAS status. Furthermore, since its market introduction over 20 years ago, extensive research has suggested several beneficial physiological roles for LactoSpore*:

GI Health

Studies have suggested a role for *B coagulans* in improvement of both acute and chronic GI symptoms due to abnormalities in intestinal flora.*[8,9] *B coagulans* is indicated for reducing discomfort of intestinal gas. In a study of adults (n=61) with post-prandial abdominal pain, distention, and flatulence but no GI diagnosis, improvement on a GI symptom rating scale was noted for 10 of 12 variables with significant improvement in three of 12 GI variables.[10] Additional studies have shown efficacy in the management of GI problems associated with infections or the use of antibiotics.*[11,12]

The effect of *B coagulans* on pain, discomfort, and bloating in patients (n=44) with irritable bowel syndrome (IBS) was evaluated over an eight-week period with statistically significant improvements noted from baseline value using a self-assessment score.[13] Adding significance to the benefits for use in IBS, a double-blind, placebo-controlled, multicenter trial evaluating the safety and efficacy of LactoSpore in IBS patients (n=36) over a 90-day period suggested that daily supplementation with two billion spores significantly decreased symptoms of vomiting, bloating, diarrhea, abdominal pain, and stool frequency ($P<0.01$).[14] This study ultimately resulted in licensure of a Canadian health claim for the use of LactoSpore to address IBS.*

Hyperlipidemia and Vaginal Health

While the evidence base supporting *B coagulans* is most notable for GI health, effects on maintaining blood lipid levels already within a healthy range have been demonstrated.[15-17] In an open-label fixed-dose trial of 17 patients with hyperlipidemia, a daily regimen of *B coagulans* for 12 weeks suggested a significant reduction in total serum cholesterol and LDL cholesterol. The level of HDL cholesterol was marginally increased with no change in serum triglyceride concentrations noted.[16] It has also been suggested that *B coagulans* plays a role in the beneficial management of non-specific vaginitis.*[18-20]

IgY Max™ Hyperimmunized Egg Powder

Microbial imbalance occurs when non-beneficial bacteria over-proliferate in the gut, taking up vital nutrients that beneficial flora need to survive.[21] As an innovative approach to modifying the composition of the microbiome, *UltraPlex Probiotic IgY* combines LactoSpore with IgY Max to help promote the attachment of beneficial flora and address non-beneficial bacteria by imparting passive immunity in the intestinal tract, thus allowing the beneficial flora to thrive.*

Decades ago, immunology researchers began investigating the possible health benefits to humans that could be achieved by the consumption of products from hyperimmunized lactating cows and laying hens.[22] Agricultural scientists soon discovered that they could simultaneously immunize a single laying hen against multiple human germs. The resulting avian immunoglobulins, known as IgY, are transferred to the egg yolk, paralleling the way human immunoglobulins (IgG) are passed to the placenta. From this discovery, a new functional food was born: the "hyperimmune egg." IgY Max is the result of special hyperimmune egg harvesting and processing techniques that result in a polyvalent, immunoglobulin-rich, dried hyperimmune egg food product that can be consumed as a dietary supplement. Hyperimmune egg provides a concentrated source of environmentally specific IgY antibodies and immune-supporting cofactors that can confer passive immunity to those who consume it.[22-27] There are over 100 patents associated with the production of hyperimmune egg and its use in animals and humans. Additionally, IgY Max is self-affirmed GRAS—a designation that affirms safe consumption—and it holds a Food Additive Master File number.*[28]

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UltraPlex Probiotic IgY

Supplement Facts

Serving Size: 2 Capsules
Servings Per Container: 60

	Amount Per Serving	%Daily Value
Calories	5	
Cholesterol	15 mg	5%
Sodium	5 mg	<1%
IgY Max™ Hyperimmunized Egg Powder	1 g	**
LactoSpore® *Bacillus coagulans* MTCC5856	10 mg (1 Billion spores)	**

**Daily Value not established.

Other Ingredients: HPMC (capsule), medium-chain triglyceride oil, silica, dicalcium phosphate, and sweet potato maltodextrin.
Contains: Egg

IgY Max™ IgY Max is a trademark of IgY Nutrition, LLC and is used under license.

LactoSpore® is a registered trademark of Sabinsa Corp.

Directions

Take two capsules twice daily with cold water, or as directed by your healthcare practitioner.

Consult your healthcare practitioner prior to use. Individuals taking medication should discuss potential interactions with their healthcare practitioner, and individuals with egg allergies should not consume this product. Do not use if tamper seal is damaged.

Does Not Contain

Wheat, gluten, yeast, corn, soy, dairy products, fish, shellfish, peanuts, tree nuts, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, or artificial preservatives.

Furthermore, in-vitro, animal, and human studies of hyperimmune egg and IgY have shown that supplemental IgY from hyperimmune egg imparts passive immunity in the intestinal tract.*[22,23,27,29-32]

An eight-week open-label pilot study (n=6) utilizing two 500 mg capsules of IgY Max two times per day explored their effect on microbial diversity (through stool analyses) and biomarkers of gut wall integrity (zonulin, histamine, and diamine oxidase) in subjects with mild-to-moderate GI complaints. Subjective data included reports of "a decrease in gas and bloating" and "feeling more energy" suggesting improved quality-of-life measures. Objective markers showed a decrease in gut permeability and an overall increase in beneficial flora.*[33]

Randomized controlled trials have suggested that IgY plays a significant role in the management of rotavirus-associated diarrhea. In a study of children (n=150) with severe diarrhea who were randomly divided into control, probiotic, and immunoglobulin groups, subjects in the immunoglobulin group had a significantly increased fecal secretory immunoglobulin A (SIgA) level after one day of treatment, a significantly decreased frequency of diarrhea and fecal rotavirus shedding after three days of treatment, and a significantly shorter disease course (4.5±1.0 vs 5.8±1.7 days; P<0.05).These results suggested that although probiotics can reduce intestinal flora imbalance and prevent secondary intestinal bacterial infection, they take a longer time to relieve clinical symptoms and cannot shorten the course of disease.[25] In an additional study, rotavirus-positive children (n=52) were randomized into IgY group and placebo IgY group, with all patients receiving standard supportive therapy for diarrhea. When compared to placebo, the IgY group had statistically significant reduction in oral and intravenous rehydration fluid intake, duration of diarrhea from day of admission, and duration of rotavirus clearance from stool from day of admission.*[27]

In addition to IgY immunoglobulins, hyperimmune egg also contains immunoregulatory factors that act directly on GI surfaces where they may influence effector cells and also circulate systemically where they act as intercellular communicators. As intercellular communicators, they are responsible for the regulation of a variety of immune, hormonal, and metabolic pathways that have widespread systemic effects.[22] Preliminary studies suggest that these immunoregulatory factors benefit cytokine modulation, joint health, blood lipid metabolism, exercise performance, and overall wellness.*[22,26]

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