Restoring Essential Intestinal Microdiversity

Ther-Biotic® Complete
Broad Spectrum, Synergistic Multispecies Probiotic Formula

Restoring Essential Intestinal Microdiversity

KLAIRE LABS™
A division of ProThera®, Inc.
Multispecies Benefits

More effective than single strains.

Numerous lines of evidence support the superiority of a multispecies probiotic formulation compared to single strains in achieving colonization and biocological transformation of the complex gastrointestinal microenvironment. Probiotics may interact in many ways to make multispecies formulations more consistently effective than monostrain or multistrain preparations. One example of this mutually beneficial interaction or synergy, termed “protocooperation”, can be observed as increased efficacy against pathogens. Combined use of multiple species enhances growth and metabolic activity of the beneficial organisms resulting in increased nutrient consumption, a well-documented mechanism by which probiotics control gastrointestinal pathogens.

The 12 synergistic probiotic species in Ther-Biotic® Complete can be expected to provide additive benefit extending far beyond the actions of the individual species.
High Potency
25 to 100 billion CFUs per dose.
The modern Western diet supplies billions fewer healthful bacteria daily than needed to maintain healthy immune system and gastrointestinal functions. Healthful probiotic bacteria must survive the passage through the highly acidic stomach and then withstand the bile salts and proteolytic acids found in high concentrations in the duodenum before they arrive in the more distal small intestine and colon. A high potency probiotic preparation helps ensure that adequate numbers of microorganisms survive to reach the distal small bowel and colon to exert their beneficial effects. The importance of consuming higher potency preparations is underscored by numerous studies that have documented a probiotic dose-dependent response for conditions such as acute diarrhea. The safety of consuming hundreds of billions of probiotics daily has been demonstrated by many studies, some of which involved immunosuppressed patients.

Ther-Biotic® Complete capsules contain 25+ billion colony forming units (CFUs).

Ther-Biotic® Complete powder contains 100+ billion colony forming units (CFUs) per 1/4 teaspoon (1 gram).

Acid Stable Matrix
Protected by InTactic®.
Ther-Biotic® Complete utilizes Klaire Labs™ proprietary InTactic® technology to protect the probiotics against stomach acid insuring that maximal numbers of viable healthful bacteria reach the small intestine and colon. InTactic® is a natural polysaccharide of marine origin that is mixed with the probiotics during production. On exposure to stomach acid, the InTactic® material forms a gel-like matrix surrounding the probiotics effectively shielding them from the acid environment. On passage into the duodenum, InTactic® breaks down, releasing live microorganisms into the intestinal lumen. InTactic® significantly increases the number of living probiotics reaching the small intestine and colon.

A Versatile Formula
Suitable for children or adults.
Anyone consuming a standard American diet will benefit from Ther-Biotic® Complete by the replenishment of essential gastrointestinal probiotics missing from the diet. Long-term probiotic supplementation is vital to the maintenance of a normal intestinal microflora. Ther-Biotic® Complete offers specific gastrointestinal microflora support during interventions known to reduce the bowel’s population of friendly, essential bacteria such as antibiotic therapy, immunosuppression, and cancer chemotherapy.

Ther-Biotic® Complete offers unsurpassed probiotic support for people with:
- intestinal dysbiosis
- irritable bowel syndrome
- inflammatory bowel disease
- malabsorption
- lactose intolerance
- increased intestinal mucosal permeability (“leaky gut”)
- infectious gastroenteritis
- diarrhea
- constipation
- allergic sinusitis
- food allergies
- vaginal dysbiosis
- recurrent urinary tract infections

Hypoallergenic Formula
Casein- and gluten-free.
Probiotics used in Ther-Biotic® Complete are cultured on a proprietary vegetable-based growth media free of dairy, wheat, and other common allergens. In addition, no sugar, artificial sweeteners, or preservatives are used.

Inulin oligosaccharide base.
Inulin is a nondigestible oligosaccharide derived from chicory root. Inulin and other nondigestible oligosaccharides, referred to as prebiotics, can be metabolized by healthful lactobacilli and bifidobacteria, stimulating their growth. Unlike some highly processed, long chain fructooligosaccharides, inulin is less likely to be used as a food source by pathogenic bacteria. Ther-Biotic® Complete contains inulin as a base ingredient in place of corn- or wheat-derived maltodextrin, commonly found in probiotic supplements. Inulin is a naturally-derived ingredient that is generally well-tolerated by the highly sensitive person.
<table>
<thead>
<tr>
<th>Species</th>
<th>Traits</th>
<th>Documented Uses*</th>
<th>Species</th>
<th>Traits</th>
<th>Documented Uses*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactobacillus acidophilus</td>
<td>Highly resistant to acid, bile &amp; pancreatic enzymes</td>
<td>• Ulcerative colitis</td>
<td>Bifidobacterium bifidum</td>
<td>Indigenous to bowel</td>
<td>• Rotavirus, antibiotic-associated &amp; C. difficile-associated diarrhea</td>
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<td></td>
<td>Antagonizes numerous bacterial pathogens</td>
<td>• Pouchitis</td>
<td></td>
<td>Low numbers in allergic infants &amp; elderly</td>
<td>• Ulcerative colitis</td>
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<td></td>
<td>Reduces intestinal carcinogenic enzymes</td>
<td>• Yeast vaginitis &amp; bacterial vaginosis</td>
<td></td>
<td>Suppresses IgE secretion</td>
<td>• Support Bifidobacterium microflora in the elderly</td>
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<td></td>
<td></td>
<td>• Irritable bowel syndrome</td>
<td></td>
<td>Activates B cells</td>
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<td></td>
<td></td>
<td>• Cholesterol reduction</td>
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<td>Enhances phagocytosis</td>
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<td></td>
<td></td>
<td>Enhances IgA response to C. difficile toxin A</td>
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<tr>
<td>Lactobacillus rhamnosus</td>
<td>Produces the greatest number of peptidases</td>
<td>• Rotavirus, antibiotic-associated &amp; C. difficile-associated diarrhea</td>
<td>Bifidobacterium longum</td>
<td>Secretes elastase inhibitor Serpin</td>
<td>• Irritable bowel syndrome</td>
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<td></td>
<td>Enhances innate &amp; acquired immunity</td>
<td>• Pouchitis</td>
<td></td>
<td>Inhibits enterotoxin E. coli binding &amp; translocation</td>
<td>• Ulcerative colitis</td>
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<td></td>
<td>Excellent adherence</td>
<td>• Urinary tract infections</td>
<td></td>
<td>Augments sIgA response to inhaled allergens</td>
<td>• Pouchitis</td>
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<td></td>
<td>Suppresses E. coli internalization</td>
<td>• Yeast &amp; bacterial vaginosis</td>
<td></td>
<td>Modulates inflammation</td>
<td>• Improved lactose tolerance</td>
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<td></td>
<td></td>
<td>• Allergies, atopy &amp; eczema</td>
<td></td>
<td></td>
<td>• Seasonal allergies</td>
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<td>Lactobacillus casei</td>
<td>Hardy, highly adaptive</td>
<td>• Ulcerative colitis</td>
<td>Bifidobacterium infantis</td>
<td>Suppresses Bacteroides vulgatus, a bacterium related to inflammatory bowel disease</td>
<td>• Necrotizing enterocolitis in infants</td>
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<td></td>
<td>Many proline-specific peptidases</td>
<td>• Pouchitis</td>
<td></td>
<td>Protects bowel against Bacteroides invasion</td>
<td>• Irritable bowel syndrome</td>
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<tr>
<td></td>
<td>Modulates innate immunity</td>
<td>• Irritable bowel syndrome</td>
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<td>• Ulcerative colitis</td>
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<td></td>
<td>Increases IgA-secreting cells</td>
<td>• Constipation</td>
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<td></td>
<td>• Pouchitis</td>
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<td>Lactobacillus salivarius</td>
<td>Indigenous to the bowel</td>
<td>• Attenuates inflammatory responses to Salmonella typhimurium</td>
<td>Bifidobacterium breve</td>
<td>Secretes lactosidase</td>
<td>• Rotavirus &amp; intractable diarrhea in infants</td>
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<td>Reduces colonic necrosis &amp; inflammation</td>
<td>• Recolonizes intestines &amp; other mucosal surfaces</td>
<td></td>
<td>Reduces Bacteroides &amp; Clostridium populations</td>
<td>• Campylobacter enteritis</td>
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<td>Enhances calcium uptake</td>
<td></td>
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<td>Stimulates B cell &amp; Peyer’s patch responses</td>
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<td></td>
<td>Supports gut barrier function</td>
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<td>Lactobacillus plantarum</td>
<td>Acid &amp; bile tolerant</td>
<td>• Recurrent C. difficile-associated diarrhea</td>
<td>Streptococcus thermophilus</td>
<td>Produces lactate, formate, acetylateddehyde, acetate &amp; other fermentation products</td>
<td>• Rotavirus &amp; antibiotic-associated diarrhea</td>
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<td></td>
<td>Down regulates proinflammatory cytokines</td>
<td>• Ulcerative colitis</td>
<td></td>
<td>Inhibits pathogen replication</td>
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<td>Supports intestinal barrier function</td>
<td>• Pouchitis</td>
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<td>Decreases premalignant lesion formation</td>
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<td>• Irritable bowel syndrome</td>
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<tr>
<td>Lactobacillus paracasei</td>
<td>Excellent acid tolerance</td>
<td>• Non-rotavirus diarrhea</td>
<td>Lactobacillus bulgaricus</td>
<td>Prevents LDL oxidation</td>
<td>• Ulcerative colitis</td>
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<td></td>
<td>Resistant to pancreatin</td>
<td>• Allergic rhinitis</td>
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<td>Down regulates TNFalpha</td>
<td>• Pouchitis</td>
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<td></td>
<td>High lactic acid production</td>
<td>• Supports healthy vaginal microflora</td>
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<td>Suppresses proinflammatory cytokine secretion</td>
<td>• Irritable bowel syndrome</td>
</tr>
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<td>Antagonizes numerous pathogens</td>
<td></td>
<td></td>
<td></td>
<td>• Cholesterol reduction</td>
</tr>
</tbody>
</table>

* Indicates that a strain of the probiotic species has been used with supportive benefit for the condition cited in one or more clinical studies.

Statements made herein have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.
Beneficial Gastrointestinal Microflora: Dietary Essentials for Good Health

The human gastrointestinal tract is host to the most densely populated microbial ecosystem known. Comprised of more than 400 identified species and at least another 400 species unknown except by ribosomal RNA sequences, this highly complex community is integral to normal human development and health.

The gastrointestinal microflora is pivotal to the immune system, provides protection against pathogenic bacteria, supplies nutrients and vitamins, facilitates mineral absorption, and metabolizes cholesterol, bile acids, hormones and drugs.

Microflora within the gut consists of indigenous native species and healthful microorganisms that colonize the bowel only when they are consumed on a regular basis. Modern Western diets are not only deficient in numerous important nutrients, but lack the beneficial bacteria that are as important to health as any required vitamin or nutrient. For example, the highly advantageous lactic acid bacterium, *Lactobacillus plantarum*, colonizes the gastrointestinal tract of 100% of people in Africa and Asia consuming traditional diets rich in plant materials.

In contrast, *L. plantarum* is found in less than 25% of Americans. Similar intestinal deficiencies of *L. paracasei* and *L. rhamnosus* in Western populations have been described.

Dietary deficiencies of healthful bacteria lead to intestinal dysbiosis or an imbalanced alteration in our normal gastrointestinal microflora with excessive populations of pathogenic microorganisms. There is a growing consensus that disruptions and derangements of our normal bowel microflora contribute to the increased incidence of allergic disorders, autoimmune diseases, irritable bowel syndrome, and inflammatory bowel diseases in Western society. It is clear that alterations of the normal intestinal balance of microorganisms due to antibiotics, immunosuppressants, toxins, and gastric acid inhibitors result in intestinal and systemic health disturbances.

*Restoring a naturally balanced gut microbial community with supplemental probiotics is vitally important for the support and maintenance of gastrointestinal and immune system health.*

It is widely agreed that probiotics are defined as “viable microbial food supplements which beneficially influence the health of humans.”

*International Life Sciences Institute Europe*
Ther-Biotic® Complete
Broad Spectrum, Synergistic Multispecies Probiotic Formula

- Ultra-Potent Formula
- 12 Live Probiotic Species
- InTactic® Acid-Stable Delivery
- Powder and Capsule Options
- Hypoallergenic

Restoring essential intestinal microdiversity

Klaire Labs™ Probiotic Certification Program
Klaire Labs’ probiotic quality assurance commitment consists of an aggressive, independent testing program that monitors and ensures the identity, activity, and hypoallergenicity of our finished products.

Genetic Identification by RNA Ribotyping
Bacterial strains in Klaire Labs’ probiotics have undergone rRNA ribotyping, a highly reproducible, precise diagnostic genetic fingerprint, to validate the specific genetic pattern in comparison to established, documented strains.

Analytical Testing for Casein/Dairy Proteins
Klaire Labs’ probiotic bacteria are cultured on a dairy-free growth media to help ensure maximum tolerance. Lack of dairy proteins has been documented using Neogen® Veritox testing, a highly sensitive technique that detects levels as low as 0.00025% (<2.5 ppm) of dairy casein.

GMP Manufacturing
Klaire Labs’ probiotics are manufactured and packaged at a state-of-the-art, GMP-compliant facility, where filtered air systems and a humidity- and temperature-controlled environment help ensure product stability and purity.

Independent Laboratory Analysis
Probiotic stability is monitored throughout all manufacturing stages. All probiotic raw materials for every batch and each finished product undergo independent laboratory analysis for probiotic enumeration, microbial content, and coliform content.

Guaranteed Potency
Routine inclusion of higher quantities of microorganisms than stated on our labels coupled with refrigerated storage and cold-packaged shipping ensure that our products retain their stated potency when properly stored and refrigerated.

ABOUT KLAIRE LABSTM
Founded in 1969, Klaire Labs specializes in the development of innovative probiotics, enzymes, and other nutraceuticals that can be used with confidence by individuals who are hypersensitive to various foods and environmental agents. All active and inactive ingredients used in Klaire products are free of common allergens, including dairy, wheat, corn, soy, yeast, and gluten, as well as artificial sweeteners, colors, flavors, and preservatives. Klaire Labs™ operates as a division of ProThera®, Inc., headquartered in Reno, NV. Klaire products are distributed exclusively through healthcare professionals.

Full private labeling and custom manufacturing services are also available.

FOR MORE INFORMATION OR TO PLACE AN ORDER, PLEASE CONTACT:

KLAIRE LABS™
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ProThera, Inc. operates a GMP 9000 registered facility certified by NSF International, an independent, third-party certification organization. GMP 9000 registration integrates both ISO 9001 and GMP registration.

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