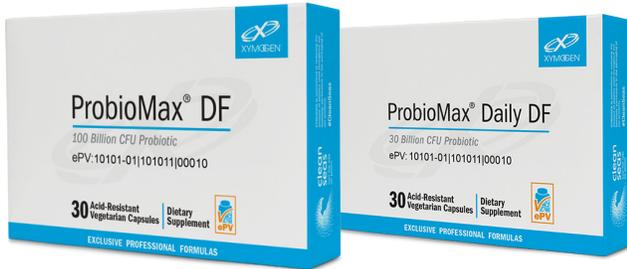


# ProbioMax<sup>®</sup> DF

30 & 100 Billion CFU Probiotics



ProbioMax<sup>®</sup> Daily DF is available in 30 capsules and 60 capsules  
ProbioMax<sup>®</sup> DF is available in 30 capsules

## Discussion

Supplementation with probiotics has many mechanisms of action that benefit health, including but not limited to: (1) supporting metabolic activity, such as the production of short-chain fatty acids and vitamins, nutrient absorption, and digestion of lactose; (2) adhering to intestinal epithelial cells to help maintain a healthy balance of organisms in the intestinal tract; (3) helping to establish populations of good bacteria after disruption in balance; (4) supporting immune function; (5) promoting intestinal epithelial cell survival; (6) supporting healthy bowel function; and (7) degrading oxalates.\*<sup>[1-8]</sup>

Common challenges associated with probiotic supplementation are maintaining stability of the organisms during distribution and shelf life and, once taken by a consumer, survival of the organisms as they travel through the digestive tract so that they reach the target tissue (intestines) alive. To help ensure stability, XYMOGEN packages the ProbioMax capsules in sealed, nitrogen-purged aluminum blister packs to serve as protection from factors proven to compromise the stability of probiotics, such as heat, moisture, and oxygen. Careful selection of organisms is another way XYMOGEN helps ensure stability. Careful organism selection, as performed for ProbioMax, is also a critical aspect of supporting digestive survival. To further support resistance to low pH and the delivery of microorganisms to the small intestines, XYMOGEN employs DRcaps<sup>™</sup> gastro-resistant capsules. These specially designed, innovative capsules help slow exposure of actives to stomach acid to promote a more targeted release.\*

**HOWARU<sup>™</sup> (*Bifidobacterium lactis* HN019<sup>®</sup>)** Discovered in 1899, *B. lactis* play a key role in the human microflora throughout a person's life. Researchers have identified strain HN019<sup>®</sup> as having excellent probiotic potential based upon its ability to survive the transit through the human gastrointestinal tract, adhere to epithelial cells, and proliferate.<sup>[6]</sup> *B. lactis* HN019<sup>®</sup> has been extensively studied, and its safety and effectiveness is well accepted.<sup>[7,8]</sup> To assess the impact of *Bifidobacterium lactis* HN019<sup>®</sup> supplementation on whole-gut transit

## Clinical Applications

- » Helps Maintain a Healthy Intestinal Microecology\*
- » Supports the Natural Immune Response\*
- » Supports Bowel Regularity\*
- » Supports Lactose Digestion\*

*ProbioMax<sup>®</sup> DF is a vegetarian, dairy- and gluten-free, four-strain probiotic totaling 100 billion CFU\* per capsule. Each vegetarian capsule is sealed in nitrogen-purged aluminum blister packs to serve as protection from factors proven to compromise the stability of probiotics such as heat, moisture, and oxygen. ProbioMax DF provides four researched strains of beneficial bacteria, including the extensively studied HN019<sup>®</sup> strain of *Bifidobacterium lactis*. These live microorganisms have proven health benefits and well-established safety, and have been tested for epithelial cell adhesion and/or resistance to low pH.\**

*To further support resistance to low pH and the delivery of microorganisms to the small intestines, XYMOGEN employs DRcaps<sup>™</sup> gastro-resistant capsules. These specially designed, innovative capsules help slow exposure of actives to stomach acid and ensure more targeted release.\**

time in adults, 100 subjects were given daily doses for 14 days of 17.2 billion colony-forming units (CFU), 1.8 billion CFU, or placebo. Decreases in mean whole-gut transit time over the 14-day study period were statistically significant in the high-dose group and the low-dose group, but not in the placebo group.<sup>[8]</sup> This level of dosing also supported other parameters of healthy GI function, as were self-reported by patient survey.<sup>[9]</sup> In another study of preschool-age children, supplementing milk for one year with 1.9 x 10<sup>9</sup> CFU per day *B. lactis* HN019<sup>®</sup> and 2.4 g/day of prebiotic oligosaccharides supported both healthy iron status and weight gain.<sup>[9]</sup> In a randomized, double-blind, placebo-controlled human dietary intervention study in elderly subjects (>60 yrs.), supplementary *B. lactis* HN019<sup>®</sup> resulted in statistically significant increases in the beneficial organisms *bifidobacteria* and *lactobacilli*.<sup>\*[10]</sup>

***Lactobacillus acidophilus* (*Lactobacillus acidophilus* La-14)** This common inhabitant of the human mouth, intestinal tract, and vagina, is also found in some traditional fermented milks (e.g., kefir) and is widely used in probiotic foods and supplements. It has a history of safe human consumption. The *L. acidophilus* La-14 strain is of human origin and has been identified as a type A1 *L. acidophilus*. *L. acidophilus* shows excellent adhesion to human epithelial cell-lines.<sup>\*[11,12]</sup>

***Lactobacillus plantarum* (*Lactobacillus plantarum* Lp-115)** This bacteria was isolated from plant material and is abundantly present in lactic acid-fermented foods, such as olives and sauerkraut. In vitro studies have shown that *L. plantarum* strain Lp-115 has excellent adhesion to epithelial cell lines.<sup>[13]</sup> In addition, *L. plantarum* is resistant to low pH conditions and survives the presence of bile at duodenal concentrations.<sup>\*[13,14]</sup>

***Bifidobacterium longum* (*Bifidobacterium longum* BI-05)** The *B. longum* BI-05 strain is well accepted as safe for human consumption. *B. longum* is resistant to low pH and bile salts and is well suited to the intestinal environment.<sup>\*[14]</sup>

\*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.

**ProbioMax® DF Supplement Facts**

Serving Size: 1 Capsule

	Amount Per Serving	%Daily Value
Proprietary Blend <i>Lactobacillus acidophilus</i> La-14® <i>Bifidobacterium longum</i> BI-05™ <i>Lactobacillus plantarum</i> Lp-115®	409 mg (50 Billion CFU <sup>1</sup> )	**
HOWARU® Bifido ( <i>Bifidobacterium lactis</i> HN019®)	167 mg (50 Billion CFU <sup>1</sup> )	**

\*\* Daily Value not established.

**Other Ingredients:** HPMC (acid-resistant capsule), microcrystalline cellulose, magnesium stearate, and silica.  
<sup>1</sup>Colony-Forming Unit

**DIRECTIONS:** Take one capsule with water daily, 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.

**DOES NOT CONTAIN:** Wheat, gluten, soy, animal or dairy products, fish, shellfish, peanuts, tree nuts, egg, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, or artificial preservatives.

**STORAGE:** Keep closed in a cool, dry place out of reach of children.

**HOWARU®**

HOWARU® and the HOWARU® logo are registered trademarks of DuPont or its affiliates.  
HN019® is a registered trademark of Fonterra™ Limited and is licensed to DuPont Nutrition Biosciences.

**ProbioMax® Daily DF Supplement Facts**

Serving Size: 1 Capsule

	Amount Per Serving	%Daily Value
Proprietary Blend <i>Lactobacillus acidophilus</i> La-14® <i>Bifidobacterium longum</i> BI-05™ <i>Lactobacillus plantarum</i> Lp-115®	174 mg (15 Billion CFU <sup>1</sup> )	**
HOWARU® Bifido ( <i>Bifidobacterium lactis</i> HN019®)	50 mg (15 Billion CFU <sup>1</sup> )	**

\*\* Daily Value not established.

**Other Ingredients:** Microcrystalline cellulose, HPMC (acid-resistant capsule), stearic acid, magnesium stearate, and silica.  
<sup>1</sup>Colony-Forming Unit

**DIRECTIONS:** Take one capsule with water daily, 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.

**DOES NOT CONTAIN:** Wheat, gluten, soy, animal or dairy products, fish, shellfish, peanuts, tree nuts, egg, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, or artificial preservatives.

**STORAGE:** No refrigeration necessary. Keep closed in a cool, dry place out of reach of children.

**HOWARU®**

HOWARU® and the HOWARU® logo are registered trademarks of DuPont or its affiliates.  
HN019® is a registered trademark of Fonterra™ Limited and is licensed to DuPont Nutrition Biosciences.

**References**

- Vanderpool C, Yan F, Polk DB. Mechanisms of probiotic action: Implications for therapeutic applications in inflammatory bowel diseases. *Inflamm Bowel Dis*. 2008 Nov;14(11):1585-96. [PMID: 18623173]
- Abratt VR, Reid SJ. Oxalate-degrading bacteria of the human gut as probiotics in the management of kidney stone disease. *Adv Appl Microbiol*. 2010;72:63-87. [PMID: 20602988]
- Masood MI, Qadir MI, Shirazi JH, et al. Beneficial effects of lactic acid bacteria on human beings. *Crit Rev Microbiol*. 2011 Feb;37(1):91-98. [PMID: 21162695]
- Turrioni S, Vitali B, Bendazzoli C, et al. Oxalate consumption by lactobacilli: evaluation of oxalyl-CoA decarboxylase and formyl-CoA transferase activity in *Lactobacillus acidophilus*. *J Appl Microbiol*. 2007 Nov;103(5):1600-09. [PMID: 17953571]
- Shu Q, Lin H, Rutherford KJ, et al. Dietary *Bifidobacterium lactis* (HN019) enhances resistance to oral *Salmonella typhimurium* infection in mice. *Microbiol Immunol*. 2000;44(4):213-22. [PMID: 10832963]
- Gopal P, et al. Effects of the consumption of *Bifidobacterium lactis* HN019 (DR10TM) and galacto-oligosaccharides on the microflora of the gastrointestinal tract in human subjects. *Nutr. Res*. 2003;23:1313-28. <http://www.daniscosupplements.com/clinical-study-bibliography.html>. Accessed June 24, 2011.
- Danisco. Clinical study bibliography & abstracts. HOWARU Bifido – Bif. lactis HN019. <http://www.daniscosupplements.com/clinical-study-bibliography.html>. Accessed June 24, 2011.
- Waller PA, Gopal PK, Leyer GJ, et al. Dose-response effect of *Bifidobacterium lactis* HN019 on whole gut transit time and functional gastrointestinal symptoms in adults. *Scand J Gastroenterol*. 2011 Sep;46(9):1057-64. [PMID: 21663486]
- Sazawal S, Dhingra U, Hiremath G, et al. Effects of *Bifidobacterium lactis* HN019 and prebiotic oligosaccharide added to milk on iron status, anemia, and growth among children 1 to 4 years old. *J Pediatr Gastroenterol Nutr*. 2010 Sep;51(3):341-46. [PMID: 20601905]
- Ahmed M, Prasad J, Gill H, et al. Impact of consumption of different levels of *Bifidobacterium lactis* HN019 on the intestinal microflora of elderly human subjects. *J Nutr Health Aging*. 2007 Jan-Feb;11(1):26-31. [17315077]
- Greene JD, Klaenhammer TR. Factors involved in adherence of lactobacilli to human Caco-2 cells. *Appl Environ Microbiol*. 1994 Dec;60(12):4487-94. [PMID: 7811085]
- Kleeman EG, Klaenhammer TR. Adherence of *Lactobacillus* species to human fetal intestinal cells. *J Dairy Sci*. 1982 Nov;65(11):2063-69. [PMID: 7153393].
- Collado MC, Meriluoto J, Salminen S. Role of commercial probiotic strains against human pathogen adhesion to intestinal mucus. *Lett Appl Microbiol*. 2007 Oct;45(4):454-60. [PMID: 17897389]
- Ding WK, Shah NP. Acid, bile, and heat tolerance of free and microencapsulated probiotic bacteria. *J Food Sci*. 2007 Nov;72(9):M446-50. [PMID: 18034741]

Additional references available upon request

All XYMOGEN® Formulas Meet or Exceed cGMP Quality Standards.

\*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.