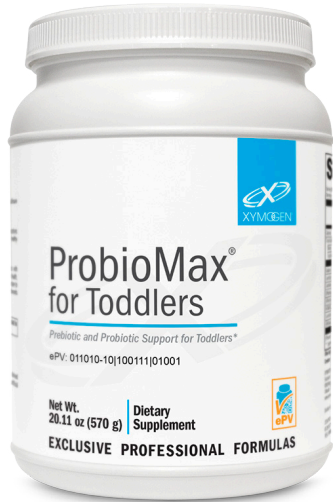


ProbioMax[®] for Toddlers

Prebiotic and Probiotic Support for Toddlers*



Available in 30 servings

Discussion

The human microbiome is an individual's unique microorganism profile. It is partially imprinted when a baby travels through the mother's birth canal and is further shaped when the baby is exposed to organisms through breastfeeding and in the environment. Like a fingerprint, no two humans have the same microbiome; this unique profile is maintained throughout the individual's life and is essential to the person's biological identity. After about the age of two, humans do not adopt any more permanent "residents" in their microbiome; additional microorganisms are essentially transient though some persist more than others.

Results of clinical studies in young children have suggested that supplemental probiotics may be beneficial to the development of gut flora, digestive health, and immune health.*^[1-8]

HOWARU[®] Protect *Lactobacillus rhamnosus* HN001[®]

The immune-responsiveness of a child's digestive system is affected by genetic predisposition, diet, state of bacterial colonization, and exposure to substances such as pathogens and medications that may disrupt the microbial balance. It is thought that dysregulation or interference with the early development of the intestinal mucosal defense system may be at the root of many intestinal and systemic health issues.^[9] A review of 13 randomized controlled trials, which included seven studies in children aged six months to 12 years, adults aged 18 to 65, and older people (N = 3720), suggested that probiotics are more effective than placebo when considering that fewer upper respiratory tract events occurred and duration was reduced in subjects taking probiotics.^[10] Additionally, a systematic review based on clinical trials in healthy children (N = 2417) from birth to age 10 suggested the use of probiotics decreased the incidence of respiratory events.*^[11]

In a series of studies over a period of six years, investigators looked at the impact of 6 billion colony-forming units (CFUs) of *Lactobacillus rhamnosus* (*L. rhamnosus*) HN001 and 9 billion CFUs of *Bifidobacterium animalis* subsp. *lactis* (*B. animalis* subsp. *lactis*)

Clinical Applications

- » Helps Promote Gut Flora Development*
- » Supports Digestive Health*
- » Supports Immune Health/Function*
- » Promotes Balance of Gut Microbiota*

ProbioMax[®] for Toddlers provides a comprehensive multi-strain combination of probiotics with 10 billion colony-forming units (CFUs) to help promote gut flora development, promote digestive health, and support immune function. Galacto-oligosaccharides (GOS)—prebiotics with a similar structure to those naturally found in breast milk—are included to promote the balance of gut microbiota towards more beneficial species.*

HN019 on immune markers associated with allergic issues and atopic sensitization. In a birth cohort (N = 474) at high-risk for skin related conditions, mothers were supplemented with HN001, HN019, or placebo from 35 weeks gestation through six months of breastfeeding, and infants were supplemented from birth until two years. The results indicated that HN001 impacted the immune markers IFN- γ , IgA, and IgE in subjects supplemented until age two, but effects were seen up to age six. Higher IgE concentration in early life is associated with allergic issues, including those of the skin, so these results suggest that the specific probiotic HN001 may be an appropriate intervention for at-risk children who need immune system support. The absence of a significant outcome in the HN019 group indicated that benefits may be species-specific.*^[12-14]

In a double-blind placebo-controlled trial in children aged one to five years (N = 398) randomized to receive 10 billion CFUs of HN001 or placebo for three months, the regular intake of the probiotic suggested modulation of intestinal immune responses; however, researchers noted that the difference between placebo and HN001 supplemented groups in frequency or severity of respiratory episodes was not significant. Fecal *Lactobacillus* counts as well as IgA levels increased significantly in the HN001 group compared to control, suggesting stimulation of the secretory immune response in the gut.*^[15]

Although more evidence is needed to draw firm conclusions, this body of research puts forward that HN001 may positively impact respiratory and immune health in young children.*

Lactobacillus reuteri (*L. reuteri*)

As a natural colonizer of the gastrointestinal flora, *L. reuteri* has also been studied for use in occasional intestinal upset. In a double-blind, placebo-controlled, randomized study in children (N = 44) at least six months old with constipation, administration of *L. reuteri* had a positive effect on stool frequency.^[16] Another double-blind study with *L. reuteri* (100 million CFUs) evaluated frequency and duration of loose stools and other health outcomes in healthy children (N = 336) aged six to

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36 months. When compared to placebo, the *L. reuteri* supplemented group exhibited less intestinal and respiratory episodes at both the three- and six-month test points.^{*[17]}

Other Strains

In a double-blind placebo-controlled study, children aged three to five years (N = 326) were assigned to receive placebo, *Lactobacillus acidophilus* (*L. acidophilus*) NCFM, or *L. acidophilus* in combination with *B. animalis* subsp *lactis*[®] Bi-07 for a six-month period. Both the single and combination test groups demonstrated less seasonal immune symptoms and number of school days missed attributable to those symptoms.^[18] In another study, an analysis was conducted at the start and after nine months of supplementation on 140 fecal samples from a larger cohort (n = 379) of children aged two to five years who were given placebo, 2 billion CFUs of *Lactobacillus paracasei* (*L. paracasei*) Lpc-37, or 5 billion CFUs of *Bifidobacterium lactis* (*B. lactis*). Following intervention, *L. paracasei* correlated positively with total *Bifidobacterium* counts and branched-chain fatty acid levels, and *B. lactis* counts were found to compare positively with total bacterial counts and negatively with short-chain fatty acid levels. Although additional research is needed to make firm conclusions, both of these findings were linked to reduced risk for loose stools in the intervention groups.^{*[19]}

Galacto-Oligosaccharides (GOS)

GOS is comprised of a short chain of galactose molecules, this type of oligosaccharide has been studied for its prebiotic effect of stimulating the development of bifidobacteria. A review of experimental and clinical data demonstrates that a prebiotic mixture of GOS modulates the intestinal flora similarly to flora modulation by human breast milk.^[20,21] Although randomized controlled trials have studied the effects of prebiotic supplementation, additional well-designed studies are warranted.*

ProbioMax[®] for Toddlers Supplement Facts

Serving Size: 2 Scoops (about 19 g)

	Amount Per Serving	%DV for Children 1 through 3 Years of Age
Calories	70	
Total Carbohydrate	19 g	13%†
Dietary Fiber	4 g	29%
Total Sugars	4 g	**
Galacto-Oligosaccharides (GOS)	5 g	**
<i>Lactobacillus reuteri</i> 1E1™	25.96 mg (1.5 Billion CFU) [‡]	**
<i>Lactobacillus acidophilus</i> NCFM [®]	8.04 mg (2 Billion CFU) [‡]	**
<i>Bifidobacterium bifidum</i> Bb-06™	5.72 mg (1 Billion CFU) [‡]	**
<i>Bifidobacterium lactis</i> Bi-04 [®]	4.18 mg (2 Billion CFU) [‡]	**
HOWARU [®] Protect <i>Lactobacillus rhamnosus</i> HN001 [®]	2.64 mg (1.5 Billion CFU) [‡]	**
<i>Lactobacillus paracasei</i> Lpc-37 [®]	2.54 mg (1 Billion CFU) [‡]	**
<i>Bifidobacterium lactis</i> Bi-07 [®]	2.24 mg (1 Billion CFU) [‡]	**

†Percent Daily Values are based on a 1,000 calorie diet.
 ** Daily Value (DV) not established.

Other Ingredients: Maltodextrin and microcrystalline cellulose.
Contains: Milk

DIRECTIONS: *Toddlers 12 months through 3 years:* 2 scoops, or take as directed by your healthcare practitioner. Mix thoroughly with food or liquid; do not mix with hot food or hot liquids.

Consult your healthcare practitioner prior to use. If the child is taking medication, potential interactions should be discussed with the child’s healthcare practitioner. This product should be given to healthy children only and not children with immune challenges.

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

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

HOWARU[®]

‡colony-forming unit

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Safety

Each of the seven probiotic strains in ProbioMax for Toddlers has a history of safe consumption in healthy young children and, based on testing, is regarded to have excellent probiotic potential. Each bacterium has been genetically characterized and properly classified by independent labs to assure quality. It should be noted that further research will help solidify the clinical applications of probiotic species, optimal duration, and dose.*

§Bifidobacterium lactis has been reclassified as *Bifidobacterium animalis* subsp *lactis*. For ease, it still tends to be referred to as *Bifidobacterium lactis*, as it is on this label. Moreover, companies trademark their particular strains by adding a letter and number code after them.

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Additional references available upon request

All XYMOGEN[®] Formulas Meet or Exceed cGMP Quality Standards.

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