PROTOCOL FOR LIFE BALANCE®

Dietary Supplement Information
for Physicians with Naturokinetics®
PRODUCT CODE: P2906
CATEGORY: WOMEN'S HEALTH

ProtoDophilus™ Woman

TECHNICAL SUMMARY

ProtoDophilus™ Woman has been specially formulated using three clinically tested probiotic strains. It features *L. rhamnosus* HN001 and *L. acidophilus* La-14 that have been shown to colonize the vaginal tract and help to maintain healthy vaginal pH when taken orally.*[1] The HN019 and HN001 probiotic strains have been shown to support healthy immune system function in women of all ages, including pregnant and nursing women.*[2] HN019 also supports GI regularity and reduces occasional gas and bloating.*[3]

Strain Information: *Bifidobacterium lactis* HN019 is a member of the *Bifidobacterium* genus, which is comprised of gram-positive, non-spore forming, anaerobic, pleomorphic bacteria that are dominant microbial residents of the colonic microbiota. *B. lactis* HN019 was originally isolated from a yogurt produced in New Zealand. This strain has been deposited with the Australian Government Analytical Laboratories (AGAL) as deposit number NM97/09513.[4]

Lactobacillus acidophilus La-14 is a gram-positive, non-spore forming, homofermentive, catalase-negative rod. It is a common inhabitant of the human intestinal tract, mouth, and vagina. This strain has been deposited in the American Type Culture Collection as SD5212.[5]

Lactobacillus rhamnosus HN001 is a gram-positive, facultatively anaerobic, non-motile and non-spore-forming, rod shaped micro-organism. It was initially isolated from a cheddar cheese produced in New Zealand. This strain has been deposited with the Australian Government Analytical Laboratories (AGAL) as deposit number NM97/09514.[6]

Allergen and Additive Disclosure: Not manufactured with wheat, gluten, soy, milk, egg, fish, shellfish or tree nut ingredients. Produced in a GMP facility that processes other ingredients containing these allergens. This product is suitable for vegetarian/vegan diets. This product is Kosher and Halal certified. It is devoid of colorant and titanium dioxide.

Delivery Form: Transparent vegetable capsules.

ROLE AS NUTRIENT/FUNCTION

In clinical studies, *Bifidobacterium lactis* HN019 has demonstrated its ability to support healthy immune function through several different mechanisms in healthy individuals, including elderly volunteers.*[4] HN019 is also able, when taken orally, to modulate the intestinal microbiota by increasing the presence of *bifidobacteria* and *lactobacilli*.*[4]

In a clinical study, both *Lactobacillus acidophilus* La-14 and *Lactobacillus rhamnosus* HN001 were able to colonize the vaginal mucosa after oral administration.*[1]

In clinical studies, consumption of *Lactobacillus rhamnosus* HN001 by healthy volunteers results in the enhancement of some aspects of natural immunity.[7-9]

Supplement Facts

Serving Size 1 Veg Capsule

Amount Per Serving

Blend of Probiotic Bacteria: *Bifidobacterium lactis* (HN019), *Lactobacillus acidophilus* (La-14), *Lactobacillus rhamnosus* (HN001)	**20 Billion CFU***

* Daily Value not established.

Other ingredients: Microcrystalline Cellulose, Hypromellose (cellulose capsule), Magnesium Stearate (vegetable source) and Silicon Dioxide.

- **Supports Vaginal Health***
- **Reduces Occasional Bloating***

SUGGESTED USAGE: Take 1 capsule daily or as directed by your healthcare practitioner.
REFRIGERATE AFTER OPENING TO MAINTAIN POTENCY.

NATUROKINETICS®

Liberation: The capsules disintegrate in water within 60 minutes.

Absorption: Probiotic bacteria are not absorbed and do not reach the bloodstream in healthy individuals.[10]

Gastrointestinal Resistance and Epithelium Adhesion:

Bifidobacterium lactis HN019: *In vitro* studies have shown that HN019 has a high tolerance to low pH conditions and high resistance to bile salts. HN019 has also demonstrated strong adhesion to human epithelial cell lines *in vitro*.[4]

Lactobacillus acidophilus La-14: *In vitro* studies have shown that La-14 has an excellent tolerance to low pH conditions and an excellent resistance to bile salts. La-14 has also demonstrated excellent adhesion to human epithelial cell lines *in vitro*.[5]

Lactobacillus rhamnosus HN001: *In vitro* studies have shown that HN001 has a high tolerance to low pH conditions and high resistance to bile salts. HN001 has also demonstrated strong adhesion to human epithelial cell lines *in vitro*.[6]

Elimination: Probiotics are eliminated in feces.[11-13]

CLINICAL VALIDATION

- In a 2-week, randomized, double-blind, placebo-controlled study in healthy women (n=40, 18-50 years old), subjects received orally either a placebo or a probiotic supplement including 10 billion CFU/d of a combination *Lactobacillus acidophilus* La-14, *Lactobacillus rhamnosus* HN001 and bovine lactoferrin (as a prebiotic). Women had increased vaginal levels of La-14 and HN001 up to 7 days after the end of supplementation (Figure 1). Their vaginal pH remained unchanged throughout the supplementation period and up to 7 days after discontinuation.*[1]

*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.

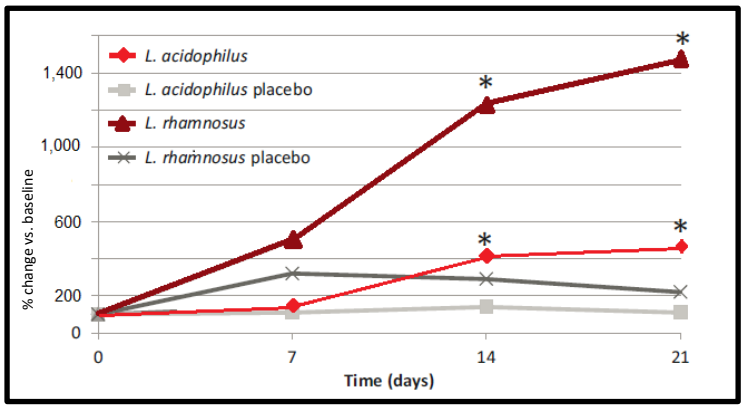


Figure 1: Vaginal presence (measured by quantitative PCR) of La-14 and HN001 after probiotic supplementation or placebo.

- In a 2-week, randomized, triple-blind, placebo-controlled study in adult volunteers (n=100, 25-65 years old), subjects received a placebo, a probiotic supplement consisting of 17.2 billion CFU/d HN-019, or a probiotic supplement consisting of 1.8 billion CFU/d of HN-019. There was a significant decrease (vs. baseline) in mean whole gut transit time (WGTT) in both probiotic groups with a 32. 6% and 24.5 % reduction in the high dose and lose dose groups respectively, but not in the placebo group ($p<0.001$).*[3] Volunteers also had a significant decrease in functional gastro-intestinal manifestations such as flatulence and gurgling in both probiotic groups.*[3]
- In a randomized, double-blind, placebo-controlled study following healthy pregnant/lactating women and their babies (n=474 mother/baby pairs) for up to 2 years, women began supplementation 2 to 5 weeks before delivery. They received 6 billion CFU/d HN001 or 9 billion CFU/d HN019 or a placebo (dextran, salt, yeast extract). The results suggest that supplementation with these probiotics during pregnancy has the potential to positively influence already normal fetal immune parameters as well as immunomodulatory factors in breast milk.*[2]

SAFETY INFORMATION

Tolerability: In clinical studies NCFM® and Bl-04 are generally well tolerated.[1,3]

Contraindications: None known.

INTERACTIONS

Drug Interactions: None known.

Supplement Interactions: None known.

Interaction with Lab Tests: None known.

STORAGE

Refrigerate after opening to maintain potency.

REFERENCES

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