HOWARU® FEMININE HEALTH

Promotes Vaginal Health and Overall Feminine Wellness

Clinically-Documented Targeted Probiotics for Vaginal Health

Women's health is a top concern for consumers which has lead dietary supplement sales for this category to consistently grow over the years. One of the main health issues women face is vaginal infections, the most common types being bacterial vaginosis and vulvovaginal candidiasis. Since a healthy human vagina is colonized predominantly with members of the genus Lactobacillus, a reduced proportion of lactobacilli in the vaginal microbiota is associated with disease or increased disease risk.

Supplementation with probiotics is an attractive approach to increasing the levels of vaginal lactobacilli and helping reduce the risk of vaginal infections. HOWARU® Feminine Health combines HOWARU® *Lacticaseibacillus rhamnosus* HN001™ and *Lactobacillus acidophilus* (HOWARU La-14™) in clinically proven formula to promote vaginal microbiota in addition to having beneficial effects in regards to bacterial vaginosis and vulvovaginal candidiasis.

Product Attributes

10B CFU

HOWARU® *Lacticaseibacillus rhamnosus HN001*™

***Lactobacillus acidophilus* (HOWARU La-14™)**

- Formulated exclusively for women's vaginal health and wellness
- Helps maintain healthy vaginal microbiota and pH
- Results seen in 7 days*

*colonization of probiotic species observed in 7 days

Immune Health **Vaginal Health**

Balanced Vaginal Microbiota

A randomized, double-blind, placebo-controlled trial has shown that after taking two probiotic capsules (5 x 10^9 CFU) once daily of HOWARU® Feminine Health containing HOWARU® *Lacticaseibacillus rhamnosus* HN001™ and *Lactobacillus acidophilus* (HOWARU La-14™) plus lactoferrin for 14 days that there was a colonization of the vagina of healthy women with these microbes and that the colonization persisted at least one week after intervention compared to the placebo (Figure 1).[1] Vaginal pH remained in the healthy range throughout the study.

In another clinical trial, 40 women with an intermediate Nugent score, indicating a perturbed vaginal microbiota, and with signs/symptoms of vaginitis/vaginosis orally consumed once daily either a proprietary mixture of 5 x 10^9 CFU of HOWARU® *Lacticaseibacillus rhamnosus* HN001™ and *Lactobacillus acidophilus* (HOWARU La-14™) in combination with 50mg of bovine lactoferrin RCX™ (Respecta®) or a placebo for 15 days. Lactobacillus species were analysed by RT-PCR from vaginal swabs at baseline and in the end of the 15-day probiotic/placebo treatment.[2]

The study showed that both species were detected in significantly higher levels from the vaginal samples at the end of intervention as compared with baseline and placebo. In addition, the Nugent score of women in the probiotic group significantly improved from intermediate at baseline to normal (P=0.0004) after 15 days of supplementation. In contrast, the Nugent score in the placebo group remained unchanged. Self-assessed vaginal symptoms (itching, discharge) decreased significantly at the end of 15d treatment compared with placebo (P<0.001) as well. Significant results from the clinical study are shown in Table 1.

Bacterial Vaginosis

Bacterial vaginosis (BV) is one of the most common types of vaginal infections faced by women. It is characterized by a depletion of beneficial bacteria (lactobacilli) and an overgrowth of atypical bacteria. A randomized, double-blind, placebo controlled trial was conducted in Romania to investigate the effectiveness of probiotics in the treatment of BV.[3]

In the clinical trial, 48 women with symptomatic BV infections were treated with metronidazole (500 mg twice daily) for seven days and were randomly assigned to take simultaneously orally either the HOWARU® *Lacticaseibacillus rhamnosus* HN001™ and *Lactobacillus acidophilus* (HOWARU La-14™) and lactoferrin formulation or placebo (two capsules/day for five days followed by one capsule/day for 10 consecutive days; induction phase).[2] The administration of study products (one capsule/day for 10 consecutive days) was repeated monthly (maintenance phase) during the six months of follow-up starting the first day of menstrual cycle as the menstrual blood increases the vaginal pH and contributes to an increased the risk of BV recurrences. The clinical cure rate of BV symptoms, microbiological cure rate (Nugent score), and BV recurrence was evaluated during the 6-month study period.

The results showed that BV-associated symptoms (vaginal discharge and itching) and the Nugent score were significantly improved, as well as BV recurrence rate was significantly reduced by the probiotic treatment group containing HOWARU® *Lacticaseibacillus rhamnosus* HN001™ and *Lactobacillus acidophilus* (HOWARU La-14™) in association with lactoferrin when compared with the placebo. A significant regression of Nugent score and resolution of symptoms were seen both during the induction phase (15 days) and maintenance phase (after 6-month follow-up). This alternative approach has been shown to represent a safe and effective adjunct for the restoration of healthy vaginal microbiota and in reducing vaginal symptoms associated with bacterial vaginosis.

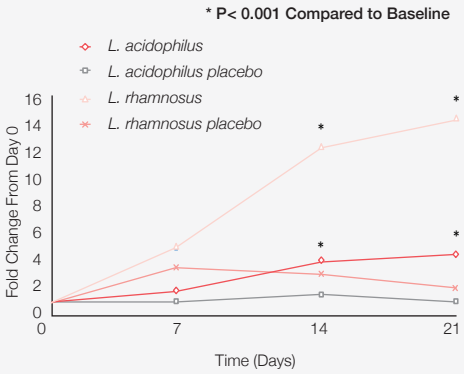

Figure 1: Vaginal recovery of healthy bacteria Adapted from DeAlberti et al. 2015. Arch Gynecol Obstet (2015) 292:861-867 DOI 10.1007/s00404-015-3711-4 .

Table 1: Significant results from the clinical trial comparing probiotic + lactoferrin group with the placebo group (Russo et al., 2018a)

Evaluation (15 Days)	Result
Vaginal colonization of HOWARU® *Lacticaseibacillus rhamnosus* HN001™ and *Lactobacillus acidophilus* (HOWARU La-14™)	• There was vaginal colonization of both species • The bacterial counts in the probiotic group was significantly higher than the placebo group and baseline
Nugent score	• There was a significant improvement from intermediate to normal score in the probiotic group from baseline (P=0.0004) • No changes from the baseline in the placebo group • Significantly lower for the probiotic group compared with the placebo group (P=0.011) at the end of the study
Vaginal symptoms (itching/discharge)	• Symptoms decreased significantly in the probiotic group compared to the placebo group (P<0.001)
Vaginal pH changes	• No change in pH between groups

Vulvovaginal Candidasis

Vulvovaginal candidasis (VVC) is a fungal infection of the vulva and vagina, which is the second most common cause of inflammation and vaginal discomfort in women.

A randomized, double-blind, placebo-controlled clinical trial involving 48 adult women assessed the clinical cure rate of vulvovaginal candidiasis (VVC) symptoms, overall cure rate, as well as the recurrences during a follow-up period of six months.[4] In the study, women with symptomatic acute episodes of VVC and a documented anamnestic history of recurrences were treated with a topical clotrimazole (100 mg) for seven days and were randomly assigned to simultaneously orally take either the probiotic mixture plus lactoferrin (active) or a placebo (two capsules/day for five days followed by one capsule/day for 10 consecutive days; induction phase). The active or placebo administration (one capsule/day for 10 consecutive days) was repeated monthly (maintenance phase) during the six months of follow-up in the premenstrual phase or luteal phase as during this time, hormonal and immunological reasons make the vagina more vulnerable to pathogens and pose a higher risk of VVC recurrences.

The results showed that after three months, symptoms of VVC (vaginal discharge and itching) were significantly improved and the recurrence rate was significantly reduced in the participants taking the probiotic-lactoferrin combination in comparison to that of the placebo until the end of the study (six months). This approach may represent a safe and effective adjunct to clotrimazole therapy for supporting and maintaining vaginal health following VVC.

References

1. De Alberti D et al., (2015) Arch Gynecol Obstet 292(4):861-867
2. Russo R et al., (2018) Arch Gynecol Obstet 298 (1):138-145
3. R. Russo, E. Karadja, and F. De Seta Beneficial Microbes 2019 10:1, 19-26
4. Russo et al. Mycoses, 2019 10.1111/myc.12883

OUR HOWARU® PROMISE

As a trusted global leader in probiotic solutions, we offer the broadest range of robust, clinically-studied strains. You can be confident that our extensive portfolio, strong consumer insights, and unmatched global support and services make us your ideal partner in probiotic innovation.

Our Strains Area:

- Backed by Science
- Identified with complete genome. Every strain has been sequenced and fully assembled
- Tested for virulence and toxigenic properties and the absence of antibiotic resistance transfer potential
- Tested for toxicity to confirm safety for human consumption
- Formulated and evaluated to ensure viability through end of shelf life
- Generally Recognized as Safe (GRAS) or FDA notified without objection as a New Dietary Ingredient
- Manufactured in the USA under FDA Good Manufacturing Practices

Exceptional Quality

- High Performance
- High Stability
- High Functionality

Our Areas of Expertise

- Women
- Weight Management
- Immune
- Oral
- Digestive
- Brain

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