



# PROBIOTICS, PREGNANCY & VAGINAL MICROBIOTA: How New Microbiome Research is Sparking Growth in the Women's Health Supplement Market

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Women are taking charge of their health like never before. As consumer awareness around the benefits of preventative health practices grows, the women's health and beauty supplement market continues to rapidly expand, with the global market projected to reach \$68.9 billion by 2026.<sup>1</sup>

sider developing probiotic supplements tailored specifically to women's health needs. By developing efficacious products, targeted to women's life stages and concerns, they'll stand out on the shelves while helping women achieve optimal vaginal and prenatal health.

## It's all about (vaginal microbiota) balance

Market demand is driven in part by emerging new research on feminine health, including how a healthy microbiota can play a critical role in women's vaginal and urinary health. As science develops around the gut microbiota's impact on various body sites -- such as vaginal microbiota -- and the impact specific probiotic strains can have on the microbiota and health, consumers are beginning to understand that probiotics offer diverse benefits, beyond traditional digestive health. In turn, women are looking to probiotics to provide natural solutions to specific health concerns, such as combatting common vaginal infections or boosting prenatal health.

Manufacturers and formulators seeking to meet market demand can con-

like probiotics, may help.

The research community is sharpening its focus on what keeps vaginal microbiota healthy, what specifically causes dysbiosis and how probiotics can help. Within the last ten years, studies have revealed that the vaginal microbiota can be categorized into several different bacterial community types. A key indicator of a healthy human vagina is a high number of *Lactobacillus* species. Specifically, the lactobacilli types predominantly colonizing the vaginal microbiota, especially in healthy women, are *L. crispatus*, *L. jensenii*, and *L. gasseri*. Reduction in the proportion of lactobacilli in the vaginal microbiota is associated with disease or increased disease risk, and women lacking abundance of these lactobacilli types in the vaginal tract are typically more prone to infection.

Vaginal infections commonly result from vaginal microbiota imbalances caused by atypical vaginal bacterial overgrowth. Antibiotics and antifungal medicines are the primary treatments for vaginal infections, but in many cases, they can cause unpleasant side effects. Oftentimes, bacterial vaginosis or vulvovaginal candidiasis recurs. A more natural solution,

biota balance and boost recovery from potential disruption.

However, formulators seeking to develop a women's health product must keep in mind that probiotic strains are not a one-size-fits-all solution. Probiotic solutions for feminine wellness should include strain-specific formulations and accurate dosing of each strain to support women through key life stages such as pregnancy, pre- or post-menopause.

Products may contain the same strains with different dosing, to address specific health needs. For example, HOWARU® Feminine Health combines *Lactobacillus acidophilus* La-14® and *Lacticaseibacillus rhamnosus* HN001™ to target vaginal microbiota balance while HOWARU® Protect Prenatal+ features different quantities of the same strains to benefit women's prenatal health. In addition to evaluating the efficacy and safety behind a product, formulators must evaluate the strains and dosing, to fully tailor the end product to their target consumer's life stage.

## The proof is in the probiotic clinical trials

Formulators seeking to develop a probiotic specifically for women's vaginal health can consider incorporating HOWARU® Feminine Health into their formulations. Researchers found that when consumed orally, the strains within HOWARU® Feminine Health can migrate to the vaginal tract and balance vaginal microbiota.

In a randomized, double-blind, placebo-controlled clinical trial<sup>5</sup>, a group of healthy women consumed two HOWARU® Feminine Health capsules once daily for 14 days. At the end of the study, women experienced a rise in vaginal *Lactobacillus acidophilus* and *Lacticaseibacillus rhamnosus* levels, which continued to increase for at least one week when compared to the placebo group.

In another clinical trial, 40 women with signs of vaginosis and an intermediate Nugent score, which indicates a perturbed vaginal microbiota, reported an increase in healthy vaginal bacteria after consuming HOWARU® Feminine Health consistently for 15 days<sup>6</sup>. Interestingly, results showed significantly higher

lactobacilli counts in the probiotic group compared to the placebo group – indicating probiotics' benefits for balancing vaginal microbiota. The women in the probiotic group also experienced a decrease in self-assessed vaginal symptoms like itching or discharge.

HOWARU® Feminine Health's effect on clinically diagnosed vaginal infections was investigated in two other separate trials. Women with either bacterial vaginosis<sup>7</sup> or vulvovaginal candidiasis<sup>8</sup> consumed HOWARU® Feminine Health, in addition to an antibiotic<sup>vii</sup> or antifungal treatment<sup>viii</sup>.

The women then continued to take the probiotic or placebo for six months as a maintenance. Both studies showed that the probiotic supplement provided significant benefits in bacterial vaginosis and vulvovaginal candidiasis management and recovery, when taken along with antibiotic or anti-fungal therapy.

The clinical trial results reveal HOWARU® Feminine Health's targeted ability to support healthy vaginal microbiota and address symptoms of recurring vaginal infections, such as bacterial vaginosis and vulvovaginal candidiasis, when used with antibiotic or anti-fungal therapy.

By incorporating products like HOWARU® Feminine Health into their own formulations, manufacturers can create an efficacious end-product, tailored specifically to women's health needs.

## Probiotics meet pregnancy

Mothers and their newborns can benefit from probiotic supplementation during pregnancy, birth and post-natal stages. Formulators developing a probiotic tailored specifically for women's prenatal health can consider HOWARU® Protect Prenatal+. This probiotic product provides benefits to help promote vaginal health, which is essential in reducing risks such as miscarriage or vaginal infections during pregnancy. It also supports the mother and child's immune health and promotes the mother's happiness and calmness.

A placebo-controlled clinical trial studied infants and their expecting mothers, with an allergy history, taking probiotic *Lacticaseibacillus rhamnosus* HN001™. The strain was delivered in capsules to mothers and infants, starting around six

days post-birth up to 2 years of age<sup>10</sup>. The capsule's powder was delivered to infants via syringe or teaspoon undiluted or mixed with fluid – once infants began with solid food, the powder was sprinkled on top. Mothers received the probiotic or placebo daily from five weeks pre-term to six months post-term, if breast-feeding, and blood and breast milk samples were collected to assess biomarkers related to immune health<sup>11</sup>. Results showed the probiotic's benefits in bolstering mother's immune marker levels and reducing cumulative prevalence of eczema in 2-year-olds -- this effect continued up to 11 years of age<sup>12</sup>.

In another study, breastfeeding mothers received a probiotic supplement with *Lacticaseibacillus rhamnosus* HN001™ or placebo prenatally from 14-16 weeks of pregnancy to delivery and postnatally for six months, if breast-feeding. The results showed *Lacticaseibacillus rhamnosus* HN001™'s consumption was associated with a significant reduction in the prevalence of gestational diabetes mellitus (GDM), especially in mothers over 35 years old with a history of GDM; and reduction in postnatal depression and anxiety scores<sup>14</sup>.

Clinical studies have long supported that probiotic supplementation provides mothers and their children with benefits throughout pregnancy, birth and beyond<sup>15</sup>. Additionally, recent studies suggest probiotics could potentially affect breast milk composition<sup>16</sup> and may support breast health in women with mastitis<sup>17</sup>, painful breast tissue inflammation while breastfeeding. Staying healthy through these stages is vital to optimal infant development, and manufacturers can help women do so naturally by incorporating clinically documented probiotic strains such as those found within HOWARU® Protect Prenatal+ into their prenatal supplement formulations.

## Strain stability over formula creativity

Besides selecting tailored, efficacious strains, there are a range of other factors to consider when developing a high-quality end-product for women's health. One of the main considerations brand owners must keep in mind is how to stand out in a marketplace crowded with similar products.

Combining healthy bacteria with popular herbal or botanical solutions is an emerging trend in probiotic supplements, and a savvy way to create a unique, personalized product. For example, cranberry is well-known for its natural benefits to lower urinary tract infection risk. Formulators can consider combining cranberry with strains such as *Lactobacillus acidophilus* La-14® to help women support vaginal and urological health, for a wholistic women's health product.

However, formulators should be aware of how combining certain ingredients can affect strain stability. More clinical research is needed to truly understand the potential synergistic benefits of various botanicals and strains and how they interact. While incorporating well-known botanicals will attract consumers, formulators must be certain that the combination has synergistic benefits and will not inhibit strain stability and efficacy.

When looking to develop tailored combination probiotic products for women's health, it's important to work with a supplier who emphasizes strain stability, product quality and safety. Emerging formats and combinations require expertise in probiotic formulation to ensure the claims on the package are valid through the end of the product's shelf-life. By partnering with a supplier experienced in developing innovative probiotic blends, formulators will be well-equipped to develop high-quality, personalized products, that remain effective throughout their shelf-life.

#### The future is female health

When it comes to understanding how specific probiotic strains benefit vaginal microbiota, researchers have just scratched the surface. As new research emerges, probiotic supplements for women are likely to become even more personalized. In the coming years, women may be able to take a test to discover their individual vaginal microbiota, allowing them to take probiotic supplements crafted specifically for their vaginal microbiota health.

Women are increasingly taking charge of their health and lives – and they're doing it via probiotics tailored to their health concerns. This is not only a trend, but a



movement that will continue to develop into the future. Manufacturers can stay ahead of this rapidly evolving market by prioritizing clinically documented strains and collaborating with a trusted, experienced strain supplier to develop effective supplements that allow women to prioritize their personal health. The future of female health, empowered by innovative probiotic solutions, is looking bright. ●

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