

# BioDoph-Fem™

Targeted Probiotic Formula for Women's  
Gastrointestinal & Vaginal Health\*



BioDoph-Fem™  
available in a 30-count  
bottle (#1286).

BioDoph-Fem™ provides two clinically validated probiotic formulations, Astarte™ and Clepius™, combined to offer broad support for women's gastrointestinal and vaginal health.\* The composition of both gastrointestinal and vaginal microbiota has been shown to be a strong predictor of the health and function of these organs, and to influence associated symptoms as well as risk of other health challenges. For example, both gut and vaginal microbiota provide a natural protective layer against pathogenic organisms through adhesion to epithelial cells as well as by producing natural antimicrobial compounds, including antimicrobial peptides and bacteriocins.<sup>1-3</sup>

Beneficial probiotics can modify the local environment, downregulate inflammatory cytokines, and increase the production of short-chain fatty acids (SCFAs) such as butyrate, which activates immune cells and increases resistance to bacterial pathogens.<sup>4,5</sup> The five *Lactobacillus* strains in BioDoph-Fem™ have demonstrated efficacy in clinical trials, including the support of a healthy microbial balance in the gastrointestinal and vaginal health and improvement in overall health and comfort.\*

## ASTARTE™

Astarte™ is a combination probiotic comprised of four *Lactobacillus* strains, *L. crispatus* LBV88, *L. rhamnosus* LBV96, *L. gasseri* LBV150N, and *L. jensenii* LBV116, isolated from healthy pregnant women in the first trimester of pregnancy.<sup>6</sup> Among asymptomatic healthy women, *lactobacilli* species are the most abundant, and are associated with a lower risk for a number of urogenital health concerns.<sup>1,7</sup> Hydrogen peroxide production by *lactobacilli*, for example, inhibits colonization of the urogenital tract

## Clinical Highlights\*

- Clinically verified strains of naturally occurring probiotic species, with support for both gastrointestinal and vaginal health.
- Astarte™ provides 4 carefully selected *Lactobacillus* strains chosen to restore healthy vaginal microbiota, with characteristics including potent hydrogen peroxide and lactic acid production, as well as the ability to inhibit the growth of common pathogens.
- Multiple clinical trials with Astarte™ demonstrate lasting colonization of *Lactobacillus* species, inhibition of pathogens, and improvement in symptoms associated with bacterial imbalances.
- Clepius™ provides *L. plantarum*, a species noted for its ability to survive in the gastrointestinal tract, to improve intestinal integrity, and upregulate short-chain fatty acid production.
- Clepius™ supplementation has been shown to help with GI symptoms including abdominal pain and discomfort, as well as GI-related quality of life, perceived stress, and stool consistency.

by *Escherichia coli* and a greater abundance of hydrogen peroxide-generating species, thereby supports a healthy urinary tract. Similarly, a vaginal bacterial imbalance is often characterized by depletion of *lactobacilli*, particularly *L. crispatus*, as well as overgrowth of obligate anaerobes such as *Gardnerella vaginalis*. Clinically this can lead to the development of vaginal discharge, pruritis (itchiness), and additional symptoms.

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The absence of hydrogen-peroxide-producing *Lactobacilli* combined with the growth of species such as *G. vaginalis* leads to a more basic pH, bacterial biofilms that are more resistant to antibiotic therapy, as well as an increased susceptibility to additional gynecological concerns.<sup>9</sup> Biofilm production by pathogenic species like *G. vaginalis* is likely the reason that antibiotics used in isolation are often ineffective, resulting in recurrence after treatment.<sup>10</sup>

The four probiotic strains in Astarte™ were selected out of 127 potential candidates, after a step-by-step selection process designed to find the optimal probiotics to promote vaginal health. Sixty-eight of the candidates were strains of the same species found in Astarte™; however, these four strains were chosen for their multiple favorable characteristics following an evaluation of probiotic safety (antibiotic resistance, lack of mucin decay, etc.), the ability to generate hydrogen peroxide and lactic acid, bile salt and acid tolerance, the ability to grow in aerobic and anaerobic environments, and the ability to inhibit the growth of a number of vaginal pathogens, specifically, *E. coli*, *G. vaginalis*, *Candida krusei*, *Candida albicans* and *Candida glabrata*.<sup>11</sup> Notably, both *L. crispatus* and *L. jensenii* are strong hydrogen peroxide producers, creating a more hostile environment for pathogenic species.<sup>12</sup>

Multiple clinical trials have been conducted to evaluate the *Lactobacilli* combination in Astarte™. In a controlled trial, pregnant women with a vaginal viral microbial imbalance received either Astarte™ combined with fructooligosaccharides (FOS) twice per day for one week, or standard therapy. Women receiving Astarte™ and FOS had significant improvements in vaginal ecology, with increases in *Bifidobacterium* and *Lactobacillus* species as well as reductions in pathogenic species, such as *E. coli*, *S. aureus*, *Proteus vulgaris*, *Candida spp.* and *Klebsiella pneumoniae*. This was accompanied by improvement in a number of clinical symptoms, including vaginal discharge, pruritis, bloating, discomfort, and constipation, as well as significant reductions in the incidence of placental insufficiency and fetal distress.<sup>13</sup>

In another double-blind placebo-controlled trial, women with a vaginal bacterial imbalance received a yogurt containing Astarte™ or one containing only acidified milk (placebo) for 4 weeks, with both groups of women also receiving a 7-day course of metronidazole. At the end of the trial, all of the women receiving Astarte™ no longer had a bacterial issue,

compared to 35% of those receiving placebo, suggesting complete resolution in all women given Astarte™. This was also accompanied by significant improvements in symptoms of vaginal discharge and odor, as well as (nonsignificant) reductions in the Nugent score compared to placebo.<sup>14</sup>

Additional clinical trials support Astarte's role in promoting a healthy vaginal microbiota and protecting against both pathogens and other specific harms. For example, 80 women with primary or secondary infertility received either Astarte™ or placebo for 4 weeks. Astarte™ use was associated with a reduction in the levels of *Ureaplasma parvum*, a mycoplasma associated with both bacterial imbalances and an increase in the risk for pre-term birth.<sup>15,16</sup> In a small double-blind and randomized pilot study conducted among postmenopausal women receiving chemotherapy for breast cancer with moderate vaginal microbial imbalances (Nugent score between 4-6), women who received Astarte™ had a significantly improved Nugent score, while this score deteriorated among women receiving placebo. Notably, chemotherapy may increase vaginal atrophy while also increasing the risk for a disproportional presence of unwanted microbes, emphasizing the importance of this non-hormonal therapy to maintain vaginal health.<sup>17</sup>

## CLEPIUS™

Clepius™ contains a specific strain of *Lactiplantibacillus plantarum* (Lpla33, formerly *Lactobacillus plantarum*) shown to support gastrointestinal health and help with symptoms such as discomfort and bloating. *L. plantarum* is a commensal bacterium in humans, previously reported to support the integrity of the intestinal barrier and to reduce intestinal permeability in experimental models and human trials, at least in part by upregulating tight junction structures and increasing SCFA production.<sup>18,19</sup> Strains of this species have been shown to upregulate gene transcription pathways for the repair of mucosal structures and integrity, including those involved in tight and adhesion junction protein synthesis and degradation.<sup>20</sup> Strains of *L. plantarum* have been found to adhere to intestinal epithelial cells, with multiple benefits for gastrointestinal health.<sup>21</sup>

In a randomized and double-blind placebo-controlled and dose-finding trial, Clepius™ was shown to normalize bowel habits and improve symptom severity among people with diarrhea-predominant gastrointestinal/bowel-related distress. Over 300 adults were enrolled in this 8-week trial and received one of two doses of Clepius™ or placebo.

The outcomes seen were positive changes in a number of symptoms such as abdominal pain severity, GI-related quality of life, and perceived stress. At the end of 8 weeks, a dose-dependent reduction in GI-related distress was observed among participants receiving Clepius™, significantly greater than placebo (-156.77 at the 10B dose, -128.45 at the 1B dose, and -58.82 with placebo). The reduction in both active groups was more than double the magnitude of the placebo, a statistical and clinically meaningful improvement. Additionally, at the end of the trial, participants' GI-severity profiles were classified as either in remission or mild in 48.1% to 72.6% of people (dose-dependent), compared to 11.1% in the group receiving placebo. Significant improvements were observed in secondary measures, including abdominal pain severity and duration, abdominal distention, IBS-QoL (Quality of life), perceived stress (measured via the perceived stress scale, PSS), and improved stool consistency. For example, 62.5% and 88.4% of people receiving Clepius™ (dose-dependent) had significant reductions in diarrheal stool form, compared to 26.3% of those in the placebo group.<sup>22</sup>



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### Supplement Facts

**Serving Size: 1 Capsule**  
**Servings Per Container: 30**

	Amount Per Serving	% Daily Value
Proprietary Probiotic Blend (providing 6 Billion CFUs)	61 mg	
ASTARTE™† Proprietary Blend:		*
<i>Lactobacillus crispatus</i> (LBV 88™), <i>Lactobacillus rhamnosus</i> (LBV 96™), <i>Lactobacillus gasseri</i> (LBV 150N™), <i>Lactobacillus jensenii</i> (LBV 116™)		
<i>Lactobacillus plantarum</i> (Lpla 33™)(CLEPIUS™)†		*

**\* % Daily Value not established**

**Other ingredients:** Microcrystalline cellulose, hypromellose (capsule), magnesium stearate, silica.

†ASTARTE™, CLEPIUS™ and logos are trademarks of Chr. Hansen A/S

Recommendation:

One (1) capsule each day as a dietary supplement or as otherwise directed by a healthcare professional.

## References

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