

# proBVformula® - innovative aid in bacterial vaginosis

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*Bacterial vaginosis (BV) is a dysbiosis of the vaginal mucosa characterized by secretions of specific odour and colour, as well as irritation, itching, painful urination, and discomfort during intercourse. The changes caused by BV are unpleasant and frustrating, so women with this disease often feel psychological discomfort. Scientific sources indicate that the prevalence of BV reaches up to 50%. [1]. Many pathologies have been associated with BV, such as second-trimester miscarriage, preterm birth, post-abortion infection, increased risk of HIV, gonorrhoea, chlamydia and trichomoniasis infections, and the development of cervical cancers. BV remains a relevant societal issue, and without proper treatment, patients' quality of life deteriorates. Therefore, it is important to diagnose diseases as early as possible, prescribe appropriate treatment and prevention measures.*

Research shows that BV develops when natural bacteria that form the vaginal microflora, such as lactobacilli, are overshadowed by the pathogenic anaerobic bacteria *Gardnerella vaginalis*. The most important structure in the pathogenesis of BV is considered to be a biofilm formed from microorganisms on the surface of the vaginal mucosa, where namely *G. vaginalis* forms the largest part. The scientific literature suggests that metranidazole-based medicines (which are considered to be among the most effective) are ineffective only due to vaginal biofilms, which require additional medicines to degrade and effectively treat BV [2, 3].

## EFFECTS OF PROBVFORMULA® ON *GARDNERELLA VAGINALIS*

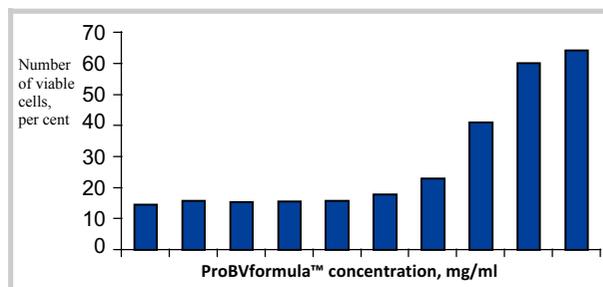
The major factor in the virulence of *G. vaginalis* is the protein vaginolysin produced by these bacteria. Vaginolysin is a protein belonging to the family of cholesterol-binding toxins, which facilitates further reproduction of *G. vaginalis* and the formation of biofilms. Based on the mechanism of action of *G. vaginalis*, it was concluded that neutralization of vaginolysin would prevent the spread of *G. vaginalis* and the formation of biofilms, thus increasing the efficacy of BV treatment.

Lithuanian scientists have been conducting research on this topic for almost a decade. During the research, a vaginolysin neutralizing antibody was developed, the fragment of which is able to “turn off” the vaginolysin-induced mechanism of *G. vaginalis* reproduction. In order to use the neutralizing antibody of vaginolysin, a fragment of this antibody was genetically engineered and *E. coli* technology was developed. This led to the development of a proBVformula® complex specifically for the neutralization of vaginolysin toxin.

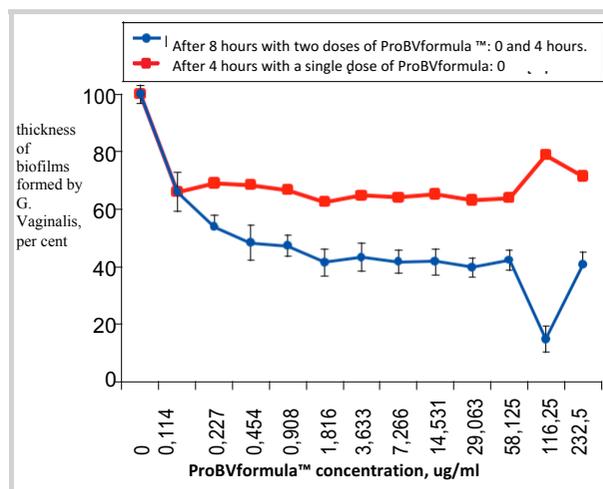
ProBVformula® protein is extracted from interstitial cells formed in *E. coli* cells using affinity chromatography and other protein purification methods. The neutralizing efficiency of ProBVformula® was tested *in vitro* by haemolytic method using human erythrocytes or by cytolytic method using HeLa cell line.

Studies have shown that proBVformula® inhibits vaginolysin-induced erythrocyte degradation and thus prevents the release of iron (the main food source for *G. vaginalis* bacteria) to the surface.

To develop effective medicines capable of preventing the spread of BV, the researchers conducted *in vivo* and *in vitro* researches.



**Dose-dependent inhibition of epithelial cell lysis with proBVformula®**



**Dose-dependent biofilm degradation with proBVformula®**

# femme future with proBVformula®



## To increase the effectiveness and prevention of bacterial vaginosis treatment

**proBVformula®** is the most advanced patented complex that neutralizes the toxin vaginolysin secreted by *Gardnerella vaginalis*, which is one of the most important causes of bacterial vaginosis.

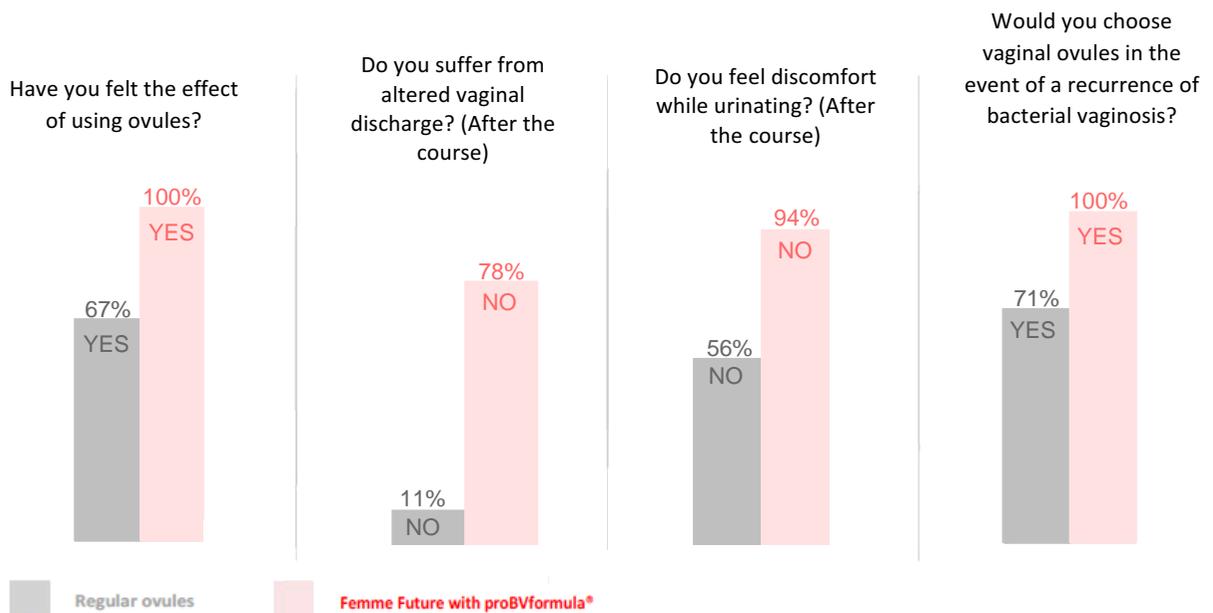
The vaginolysin neutralizing complex is in composition of **Femme Future with proBVformula®** vaginal ovules and intimate hygiene cleansers.

Manufacturer and distributor in Lithuania: UAB Fermenteka A. Goštauto str. 8-207, LT-01108 Vilnius

For more information:

[www.femmefuture.lt](http://www.femmefuture.lt) | [www.probvformula.com](http://www.probvformula.com)

## Femme Future ovules with proBVformula® work more effectively than the same ovules without proBVformula® while operating on the regulation of vaginal pH (1)



1. Medical market study performed with **Femme Future with proBVformula®** ovules. More information about the research [www.femmefuture.lt](http://www.femmefuture.lt)

# Pharmacy pages

The neutralizing activity of ProBVformula® vaginolysin was evaluated by neutralizing the toxin vaginolysin in epithelial cells, thus preventing the formation of biofilms formed by *G. vaginalis*.

## INCREASING THE EFFICIENCY AND PREVENTION OF BACTERIAL VAGINOSIS TREATMENT

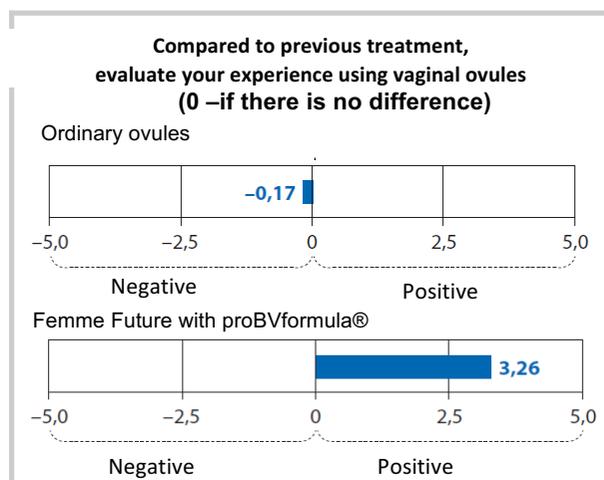
Products Femme Future with proBVformula® containing the aforementioned innovative vaginolysin neutralizing complex have been launched. Vaginal ovules Femme Future with proBVformula®, the effectiveness of which has been proven by medical market research, have attracted great interest in Lithuania and abroad. The research was performed in collaboration with Lithuanian gynaecologists, during which vaginal ovules Femme Future with proBVformula® were compared with commonly used ovules on the market, which only regulate vaginal pH. The study involved 28 women with bacterial vaginosis. The study showed that 100 percent of women who have used the ovules Femme Future with proBVformula® have felt their positive effects.

As much as 74 percent of women experienced the positive effects of the ovules Femme Future with proBVformula® as soon as they were started or during use, whereas the effects of regular ovules were felt only at the end of the course.

The results have showed that 78% of women taking Femme Future with proBVformula® no longer suffered from altered vaginal discharge. Only 11% of women who have used regular ovules did not complain of this symptom.

As many as 94% of women, who have used Femme Future with proBVformula®, did not feel any discomfort during urination. This symptom did not bother only 56% of women who have used regular ovules.

Study participants were also asked to rate their experience with vaginal ovules in comparison with previously tested measures to reduce the symptoms of BV. The results showed that **Femme Future with proBVformula®** ovules were evaluated more positively than the measures previously used by women - on a scale from -5 to +5, rating +3.26. Meanwhile, the rating of regular ovules is -0.17.



Medical market research has shown that vaginal ovules containing the vaginolysin neutralizing complex proBVformula® are more effective than regular ovules, which only regulate vaginal pH.

Products Femme Future with proBVformula® to increase the effectiveness and prevention of BV treatment are available at pharmacies.

For more information on medical market research and Femme Future with proBVformula®, visit [www.femmefuture.lt](http://www.femmefuture.lt) and [www.probvformula.com](http://www.probvformula.com)

## LITERATURE

1. Patterson JL, Girerd PH, Karjane NW, Jefferson KK. Effect of biofilm phenotype on resistance of Gardnerella vaginalis to hydrogen peroxide and lactic acid. *Am J Obstet Gynecol.* 2007; 197(2):170.e-7.
2. Pleckaityte M, Mistiniene E, Lasickiene R, Zvirblis G, Zvirbliene A. Generation of recombinant single-chain antibodies neutralizing the cytolytic activity of vaginolysin, the main virulence factor of Gardnerella vaginalis. *BMC Biotechnol.* 2011; 11:100. doi: 10.1186/1472-6750-11-100.
3. Verwijs MC, Agaba SK, Darby AC, van de Wijgert JHHM. Impact of oral metronidazole treatment on the vaginal microbiota and correlates of treatment failure. *Am J Obstet Gynecol.* 2019. pii: S0002-9378(19)31007-5. doi: 10.1016/j.ajog.2019.08.008. [Epub ahead of print].