

Consortium of Biologically Active Substances in Biotechnological Products and Their Clinical Trial

Lobach Evgenia Yurievna, Tokhiriyon Boisjoni*, Poznyakovsky Valery Mikhailovich, Cherentsova Galina Georgievna, Agababayev Mushfiq Saday Oglu

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Abstract

This article examines approaches to the comprehensive treatment and prevention of colpitis and vulvovaginal candidiasis (VVC), with a focus on the use of dietary supplements (DS). The crucial role of vaginal microflora imbalances in the development of colpitis is highlighted, justifying the use of probiotics and biocomplexes. Specific attention is given to various DS formulations, such as a Phytocomplex with black cumin oil, an Isoflavone Complex with Probiotics, a Biocomplex with fermented dietary fiber, an Intimate Mucous Membrane Care Spray, and a Biocomplex for metabolic detoxification and intestinal biocenosis correction. The composition of these DS, including plant components, probiotic strains, vitamins, microelements, and other biologically active substances, is detailed. The mechanisms of action of DS components, like the antioxidant, anti-inflammatory, and antimicrobial properties of flavonoids, are discussed, along with the role of probiotics in restoring vaginal and intestinal microflora.

Furthermore, the results of a clinical study evaluating the effectiveness of different treatment regimens using these DS in patients with chronic colpitis are presented. The study demonstrates that the proposed treatment programs, with various DS combinations, effectively alleviate symptoms and improve laboratory parameters, particularly by normalizing the microflora and eliminating pathogens. This suggests the potential of these programs for comprehensive treatment and prevention of colpitis, VVC, and other conditions associated with microbiota imbalances.

Keywords: Colpitis, Probiotics, Vaginal microflora, Dietary supplements, Detoxification

Lobach Evgenia Yurievna

Department of Tourism and Service Sochi State University, Sochi, Russia.

Tokhiriyon Boisjoni*, Cherentsova Galina Georgievna, Agababayev Mushfiq Saday Oglu

Department of Management, Entrepreneurship and Engineering, Ural State University of Economics, Ekaterinburg, Russia.

Poznyakovsky Valery Mikhailovich

Scientific and Educational Center for Applied Biotechnology and Nutrition, Kemerovo State Medical University, Kemerovo.

*E-mail: tohiriyoni@gmail.com

Introduction

Colpitis is an inflammation of the vaginal mucosa caused by the proliferation of pathogenic and opportunistic microflora (Vasiliev *et al.*, 2015; Umar Abdulkadir *et al.*, 2025). It is the most common gynecological disorder, with 85% of women of all ages having visited a gynecologist at least once in their lives for this reason (Ilina *et al.*, 2019).

The risk of developing colpitis is based on the growth of bacteria and fungi that disrupt the vaginal microflora (Ravel *et al.*, 2011; Muzny & Schwebke, 2016). Therefore, one effective means of prevention and comprehensive treatment of colpitis and its chronic form, vulvovaginal candidiasis (VVC) (Dhanasekar *et al.*, 2022; Graefen *et al.*, 2023; Nyirjesy & Sobel, 2024), is the use of probiotics biocomplexes with targeted action (Martinez *et al.*, 2019; Jakubowski *et al.*, 2023; Patel *et al.*, 2023).

Probiotic biocomplexes can help restore the natural balance of microflora by introducing beneficial bacteria that compete with pathogenic organisms for resources and space (Makhoahle & Gaseitsiwe, 2022; Borisova *et al.*, 2023; Chen *et al.*, 2023). These probiotics can enhance the immune response, reduce inflammation, and promote the production of antimicrobial substances, all of which are crucial in preventing the overgrowth of harmful bacteria and fungi (Borgdorff *et al.*, 2011; Khameneh *et al.*, 2021; Chidambaranathan & Culathur, 2022; Kwatra *et al.*, 2024).

In addition to probiotics, maintaining proper hygiene and avoiding irritants such as douches, scented soaps, and tight-fitting clothing can further support vaginal health (Serrano *et al.*, 2019; Canassa & Baldin, 2022; Perrine *et al.*, 2023). A balanced diet rich in prebiotics—found in foods like garlic, onions, and bananas—can also nourish beneficial bacteria and promote their growth (Després *et al.*, 2023; Lobach *et al.*, 2023; Pramod *et al.*, 2025).

For those already experiencing symptoms of colpitis or VVC, a multifaceted approach to treatment is essential (Vieira-Baptista *et al.*, 2021; Bulusu & Cleary, 2023; Ilina *et al.*, 2023; Shaiba *et al.*, 2024). This may include the use of antifungal medications for immediate relief, alongside a regimen of probiotics to help restore balance in the long term (Martinez *et al.*, 2019; Kızılcı *et al.*, 2024; Samaranyake *et al.*, 2024). Regular consultations with a



healthcare provider can ensure that individual treatment plans are tailored to specific needs and conditions.

Ultimately, fostering a healthy vaginal environment through the use of probiotics, dietary adjustments, and mindful hygiene practices can significantly reduce the risk of colpitis and improve overall reproductive health (Bhakta & Moran, 2020; Endres, 2020; Muhamadiev *et al.*, 2020; García & Jaramillo, 2023; Ingle *et al.*, 2023; Suchońska *et al.*, 2025).

Materials and Methods

Comprehensive nutritional programs with specialized products in the form of dietary supplements have been developed. These products contain biologically active substances that affect most of the factors involved in the development of VVC and other forms of chronic colpitis. They possess synergistic properties, working together to address various aspects of the conditions.

The Phytocomplex with black cumin oil contains the following formula ingredients: black cumin oil (linoleic acid, omega-6); magnesium caprylate (caprylic acid); clove CO-2 extract; cinnamon essential oil; garlic essential oil.

The recipe for the Isoflavone Complex with Probiotics includes isoflavones fermented by a consortium of strains (*Lactobacillus casei* ARTB-114, *Lactobacillus fermentum* ARTB-205, *Bifidobacterium breve* ARTB-129, *Bifidobacterium breve* ARTB-212, and *Bifidobacterium longum* ARTB-113 -113). It also contains selective dry bacterial biomass BB-Br (containing bacteria of the *Bifidobacterium* group *breve* ARTB-129), selective dry bacterial biomass BB-An (containing bacteria of the *Bifidobacterium* group *animalis* ARTB-116), selective dry bacterial biomass LB-Fm (containing bacteria of the *Lactobacillus* group *fermentum* ARTB-101), and selective dry bacterial biomass LB-Gs (containing bacteria of the *Lactobacillus* group *gasseri* ARTB-394). Additionally, it includes red clover grass extract (isoflavones), soy isoflavones, 5-hydroxytryptophan, dry liposomal substance with apple extract (phloridzin), sodium ascorbate (vitamin C); quercetin, angelica extract 1%, pyridoxal-5-phosphate (vitamin B6), cholecalciferol 100 IU/mg (vitamin D3), riboflavin (vitamin B2); L-methylfolate calcium folacin (vitamin B9), methylcobalamin (vitamin B12).

The Biocomplex with fermented dietary fiber includes the following components: a fermented mixture containing *Bifidobacterium animalis*, *Bifidobacterium adolescentis*, *Lactobacillus acidophilus* (fiber: corn, buckwheat, rice, flax, citrus, apple; puree: zucchini, apple, carrot, pear; mushrooms: lion's mane, *ganoderma lucidum*, oyster mushroom, shiitake; flavonoids: turmeric extract, rutin, quercetin, hesperidin, grape seed extract; apple pectin, gum arabic); apple dietary fiber; fibergum B (dietary fiber); guar gum (dietary fiber); arabinogalactan - lavitol (dietary fiber); trehalose; tryptophan; pomegranate fruit extract; terminalia *Chebula* extract (polyphenolic substances); lyophilized selective dry bacterial biomass BB- Br *B. breve* ARTB-129; lyophilized selective dry bacterial biomass BB -Ln *B. longum* ARTB-184; lyophilized selective dry bacterial biomass LB- Cs *L. casei* ARTB-182; selective dry bacterial biomass LB- Rt *Lactobacillus reuteri* ARTB-195; selective dry bacterial biomass LB- S1 *Lactobacillus*

salivarius ARTB-142; selective dry bacterial biomass BB- Bf *Bifidobacterium bifidum* ARTB-187; selective dry bacterial biomass LB-Pl *Lactobacillus plantarum* ARTB-135; selective dry bacterial biomass BB-Lc *Bifidobacterium lactis* ARTB-112; black tea extract (tannins); dry apple extract; calcium butyrate; oligopeptane ; D-mannose; L-fucose ; D-ribose; PABA-ta; lysate propionic acid bacteria with selenium " Propioselen " (selenium); silymarin (flavonolignans); trans-resveratrol.

The plant-based ingredients in the dietary supplement contain fiber, macro- and micronutrients, and flavonoids. Flavonoids are important naturally biologically active substances that promote immunity and resistance to various harmful factors, including those of bacterial, fungal, and viral origin. Flavonoids and their metabolites have been shown to exhibit antioxidant, anti-inflammatory, antitumor, neuroprotective, antidiabetic, antimicrobial, and antithrombotic activities. They are also effective in cardiovascular, pulmonary, and other diseases. Flavonoids interact with the intestinal microbiome, and disruption of this interaction plays a significant role in the development of inflammatory gastrointestinal diseases and other pathologies.

The components of the biocomplex are metabolized by strains of microorganisms that act as promoters.

The content of probiotic bacteria in the supplement is at a level of at least $1 \cdot 10^8$ CFU/gram.

The Intimate Mucous Membrane Care Spray is a comprehensive probiotic for women's health. It contains a consortium of specialized vaginal strains of lacto- and bifidobacteria aimed at restoring and maintaining normal vaginal flora. It includes selective dry bacterial biomass of the LB-Ac series (containing bacteria of the *Lactobacillus* group *acidophilus* ARTB-130); selective dry bacterial biomass LB-Fm series (containing bacteria of the *Lactobacillus* group *fermentum* ARTB-101); selective dry bacterial biomass LB-Cs series (containing bacteria of the *Lactobacillus* group *casei* ARTB-114); selective dry bacterial biomass LB - Gs (contains bacteria of the *Lactobacillus* group *gasseri* ARTB -394); selective dry bacterial biomass BB - Br series (containing bacteria of the *Bifidobacterium* group *breve* ARTB - 129); selective dry bacterial biomass BB - An (containing bacteria of the *Bifidobacterium* group *animalis* ARTB -116); subtimim lyophilized ; dry hydrolyzed biomass "Ultralysate peptide LB-Cs" (based on *Lactobacillus casei* ARTB -114); dry hydrolyzed biomass "Ultralysate peptide LB-SI" (based on *Lactobacillus salivarius* ARTB-142); dry hydrolyzed biomass "Ultralysate peptide LB-Pl" (based on *Lactobacillus plantarum* ARTB-135); lactic acid 60%; inulin.

The microorganisms included in this dietary supplement formula were isolated from the vagina and distal urethra of a healthy woman. They produce hydrogen peroxide, lactic, acetic, formic, and propionic acids, as well as polymyxins and antibiotic-like bacteriocins, which exhibit a high degree of antagonism to fungal, pathogenic, and opportunistic microflora and are active against cocci.

In addition to live probiotic strains, the complex includes active metabolites of probiotic microorganisms — peptide ultralysates,

which activate phagocytosis and other factors of local and general immunity.

Inulin, which is part of the dietary supplement, is a prebiotic and provides a nutrient medium for probiotic microorganisms.

Subtizin, sold as a metafiltrate of a special strain of *Bacillus subtilis*, contains a wide range of antibacterial peptides and enzymes active against gram-positive, gram-negative pathogens and fungi.

Metabolites of cell-free culture fluid of a special strain of *Bacillus subtilis* include a composition of biologically active substances: lysozyme, bacteriocins, catalases, antibiotic-like substances, beta-glucanases, polypeptides, lipopeptides, etc., which exhibit bactericidal and bacteriostatic effects on pathogenic, opportunistic microorganisms and fungi, without affecting the beneficial microflora of the intestine and vagina.

Lactic acid maintains the natural pH level and microflora of the vagina.

The product achieves its therapeutic effect through a combination of active strains of lactic acid bacteria in the vagina, resulting in a decrease in vaginal pH to 3.8-4.4. This leads to the active suppression of the growth and reproduction of pathogenic bacteria, as well as the restoration of the natural vaginal microflora and physiological balance.

Lactobacillus proliferation and vaginal recolonization begin after the first use of the dietary supplement. The probiotic strains in the product produce lactic acid, maintain the vaginal acid balance, and prevent the proliferation of pathogenic, opportunistic, and fungal bacteria that can cause infectious and inflammatory diseases.

The formula of the Biocomplex for metabolic detoxification and intestinal biocenosis correction includes: postbiotic metafiltrate immobilized on zeolite; natural zeolite ST (0.25-0.40 mm) (iron); dry cell-free bacterial filtrate (*L. delbrueckii* subsp. *bulgaricus* ARTB-131); Iceland moss extract 10% (usinic acid 10%); grapefruit extract, 95% (flavonones); cellulase; papain; aerosil 380; rutin; lysozyme hydrochloride.

This dietary supplement contains modified sorbents capable of neutralizing bacterial endotoxins, such as lipopolysaccharides, beta-glucans, and cell wall peptides from both gram-positive and gram-negative pathogenic bacteria and fungi. The modified sorbents specifically target gram-negative lipopolysaccharides, which are considered the most potent endotoxins. Unfortunately, the human intestinal enzyme system is unable to effectively break down these toxins/ As a result, when they enter the bloodstream, they trigger the immune system and lead to systemic aseptic inflammation. This process is further exacerbated by leaky gut syndrome, a condition in which a lack of healthy gut bacteria allows undigested protein residues to pass through the intestinal wall and into the bloodstream. These residues are also toxic and contribute to the inflammatory response. This combination can result in severe intoxication (poisoning) that is not necessarily linked to the consumption of poor-quality food.

The biocomplex can be used for prevention and as part of complex therapy for various conditions, including candidiasis of different localizations, endotoxemia, dysbacteriosis, intestinal infections, atopic dermatitis, acne, allergies, and other gastrointestinal disorders. It is also beneficial for aseptic inflammatory reactions, alcohol and food intoxication, prevention of infectious complications, and improving quality of life during chemotherapy or radiation therapy. It can help with viral and bacterial infections and their complications, as well as pre- and postoperative inflammatory processes.

Results and Discussion

The study examined the effectiveness of administering developed dietary supplements programmatically for chronic colitis, including vulvovaginal candidiasis.

Twenty patients were involved in the study, divided into two groups of ten, with ages ranging from 30 to 41 years. All patients had complaints of vaginal discomfort, intermittent itching, and unexplained discharge, for which they had received various treatments with vaginal medications in the past.

Laboratory parameters prior to the study indicated the presence of a chronic inflammatory process: flora smear showed mixed flora with cocci, coccobacilli, spores, mycelium of fungi, yeast cells, and leukocytes at 15-20 units (with a norm of 10-15 units), as well as a large amount of squamous epithelium in the field of vision; femoflor indicated the presence of opportunistic microorganisms, such as cocci, streptococci, *Gardnerella*, *Candida* at 105 CFU and 107 CFU, and a decrease in *Lactobacilli* to 104 CFU; coprogram showed the detection of iodophilic flora (fermentation bacteria) and *Candida*; hydrogen index was at 4.5-5.0 units (with a norm of 3.7-4.5 pH units).

Tables 1 and 2 present the treatment programs and regimens for each group.

Table 1. Group 1 (Program 1)

DS	Method of administration and dosage
Phytocomplex with black cumin oil	Take 1 capsule orally 3 times a day during or immediately after meals. The treatment course lasts 2 months. Do not chew or open the capsule.
	Take 1 capsule orally twice a day (in the morning, 30 minutes before meals, and in the evening before bedtime).
Isoflavone Complex with Probiotics	The course of treatment lasts for 2 months.
	Store in the refrigerator at a temperature of +2 to +10°C. Do not take simultaneously with the dietary supplements "SorbioEnzyme" and "Candy Complex".

Intimate Mucous Membrane Care Spray	Once a day, in the evening before bed. 5 intravaginal sprays as directed. The treatment should last for 10 days. Store the stick-packets in the refrigerator at a temperature of +2 to +10°C. Before the procedure, make sure to wash your hands thoroughly with warm water without soap, and dry them with a clean towel. Cut the top of the stick pack at a 45° angle with scissors, then carefully pour the contents into the bottle. Add 15 ml of boiled water at room temperature (or water for injection), close the cap, and shake vigorously until all clumps of powder are completely dissolved. Prime the nozzle by performing a few test pumps to prime the nozzle until a uniform spray appears. Lie on your back and insert the nozzle into the vagina. Press the nozzle valve to perform 5 sprays, holding the bottle upright. The design of the nozzle ensures even irrigation of the vaginal walls. Carefully remove the nozzle, lie quietly for 10-15 minutes. Wash the spray nozzle with soap and water, dry it, and store it in the enclosed plastic bag. Store the bottle in the refrigerator at +2/+10°C for up to 10 days until next use. Do not allow the contents of the bottle to freeze. Shake the bottle vigorously before each use to ensure potency is not lost. If you prefer not to use the cold spray, you can warm the bottle in your hands or let it sit at room temperature. Avoid heating the bottle with its contents in hot water or a microwave, as this can cause it to lose potency.
	Take 2 heaping tablespoons (20 grams) orally twice daily between meals. Dissolve the powder in 200 mL of room-temperature drinking water. It is recommended to start with small amounts (half the single dose per 100 ml of water), gradually increasing the dosage to two servings per day. The number of doses may be changed upon the doctor's recommendation. The treatment course lasts for 2-months.
	Take 1 capsule orally 2 times a day, either during meals or immediately after. The treatment course lasts for 2-months. Do not chew or open the capsule.

Table 2. Group 2 (Program 2)

DS	Method of administration and dosage
Phytocomplex with black cumin oil	Take 1 capsule orally 3 times a day during or immediately after meals. The treatment course lasts 2 months. Do not chew or open the capsule.
Isoflavone Complex with Probiotics	Take 1 capsule orally twice a day (in the morning, 30 minutes before meals, and in the evening before bedtime). The course of treatment lasts for 2 months.

Intimate Mucous Membrane Care Spray	Store in the refrigerator at a temperature of +2 to +10°C. Once a day, in the evening before bed. 5 intravaginal sprays as directed. The treatment should last for 10 days. Store the stick-packets in the refrigerator at a temperature of +2 to +10°C. Before the procedure, make sure to wash your hands thoroughly with warm water without soap, and dry them with a clean towel. Cut the top of the stick pack at a 45° angle with scissors, then carefully pour the contents into the bottle. Add 15 ml of boiled water at room temperature (or water for injection), close the cap, and shake vigorously until all clumps of powder are completely dissolved. Prime the nozzle by performing a few test pumps to prime the nozzle until a uniform spray appears. Lie on your back and insert the nozzle into the vagina. Press the nozzle valve to perform 5 sprays, holding the bottle upright. The design of the nozzle ensures even irrigation of the vaginal walls. Carefully remove the nozzle, lie quietly for 10-15 minutes. Wash the spray nozzle with soap and water, dry it, and store it in the enclosed plastic bag. Store the bottle in the refrigerator at +2/+10°C for up to 10 days until next use. Do not allow the contents of the bottle to freeze. Shake the bottle vigorously before each use to ensure potency is not lost. If you prefer not to use the cold spray, you can warm the bottle in your hands or let it sit at room temperature. Avoid heating the bottle with its contents in hot water or a microwave, as this can cause it to lose potency.

The study results indicate that the tested programs help eliminate the symptoms of chronic colpitis and VVC, reduce the severity of clinical manifestations in chronic colpitis, are well tolerated, and are recommended for the prevention of colpitis and VVC. Additionally, they are recommended for the treatment of chronic colpitis, mild symptoms, and changes in gastrointestinal function (microflora imbalance). The programs can be recommended for use as adjunctive treatment during the acute phase of colpitis and VVC (Table 3).

Table 3. Results of the study before and after program treatments

Indicator	Before treatment	Group 1 after treatment (Program 1)	Group 2 after treatment (Program 2)	Norm
Subjective sensations	Discomfort, itching in the vaginal area	Complaints of discomfort in the vaginal area have completely disappeared, there is no itching.	Complaints of discomfort in the vaginal area have completely disappeared, there is no itching.	-

Smear (leukocyte)	15-20 units	10-15 units	Up to 15 units	10-15 units
Smear (flora)	Rods, cocci, coccobacilli, spores, and mycelium of yeast	Sticks	Rods, coccobacilli	Sticks
Femoflor-16 (Lactobacillus)	10 ⁴ CFU	10 ⁷ CFU	10 ⁶ CFU	10 ⁷ -10 ⁸ CFU
Femoflor-16 (pathogenic flora)	10 ⁵ and 10 ⁷ CFU	10 ³ and 10 ⁴ CFU	10 ³ CFU	10 ⁴ and 10 ³ CFU
pH-metry	pH units	pH units	pH units	pH units
Coprogram	Yeast mycelium and spores, iodophilic bacteria	Absence of pathogenic flora	Yeast is detected	Absence of pathogenic flora

Program 1 showed greater effectiveness compared to Program 2 due to the inclusion of a fermented fiber complex. This complex normalizes intestinal and vaginal microflora, improves the survival and diversity of probiotic microorganisms, and utilizes a biocomplex for metabolic detoxification and biocenosis correction, which helps eliminate pathogens in the intestines.

The Phytocomplex with black cumin oil inhibits the growth and proliferation of pathogenic and fungal flora in the intestines. When used as part of a combination therapy, it effectively combats fungal infections and pathogenic microorganisms, normalizes the intestinal and vaginal microflora and mucous membranes, and eliminates the unpleasant symptoms of colpitis, such as itching, irritation, and discharge. "Candy Complex" has no impact on the probiotic microflora and does not inhibit the growth of beneficial probiotic bacteria.

The Isoflavone Complex with Probiotics helps restore normal intestinal and vaginal microflora, which is hormone-dependent. When used as part of a combination therapy, it can assist in eliminating chronic colpitis and VVC symptoms, reducing the severity of clinical manifestations and associated inflammatory processes. It is recommended for preventing colpitis and VVC, as well as treating chronic colpitis, mild symptoms, and gastrointestinal function changes (microflora imbalance). It is suggested as an adjunct treatment during the acute phase of colpitis and VVC, and for normalizing the functioning of the female genitourinary system.

This intimate care spray works to normalize vaginal microflora and maintain physiological balance by regulating acidity and inhibiting the growth of pathogenic bacteria. It is recommended as part of a comprehensive treatment program for female reproductive system disorders, such as colpitis and vulvovaginal candidiasis.

The Biocomplex with Fermented Fiber helps to normalize digestion and promotes the colonization and restoration of

intestinal and vaginal microflora. It enhances the survival and establishment of probiotic microorganisms in the intestines and vagina, while also increasing their diversity. Additionally, it has antifungal and antimicrobial effects against pathogens associated with colpitis and vaginal infections, as well as anti-inflammatory properties.

The Biocomplex for metabolic detoxification and correction of intestinal biocenosis disrupts the cell walls of pathogenic and opportunistic bacteria and fungi, leading to their demise. It also absorbs and eliminates the remnants of damaged bacterial and fungal cell membranes, reducing their toxic impact on the body. This DS is used in treating female reproductive system disorders, like colpitis and vulvovaginal candidiasis. It can also be recommended as part of a comprehensive treatment plan for preventing and treating candidiasis in various areas of the body, endotoxemia, dysbacteriosis, atopic dermatitis, allergies, and acne caused by imbalances in gastrointestinal microflora.

Conclusion

In conclusion, both programs using dietary supplements showed a positive effect in alleviating the symptoms of chronic colpitis and vulvovaginal candidiasis. However, the program utilizing the fermented fiber complex demonstrated greater effectiveness by normalizing intestinal and vaginal microflora. Further research on the individual components and their combinations is recommended to enhance the treatment and prevention of these conditions.

The formula and technology of the developed dietary supplement have been tested at the facilities of Art Life company in accordance with international standards ISO 22000, 9001, and GMP regulations. This ensures the stability of the quality characteristics of the products manufactured and builds consumer trust.

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