



## GYNALAC Vaginal Gel

GYNALAC is a vaginal pH regulator, with a double-mode of action, designed to help relieve and prevent symptoms of Bacterial Vaginosis (BV) and non-specific vaginitis, such as abnormal vaginal discharge and odor, dryness, itchiness, and vaginal discomfort, while providing a moisturizing effect that promotes healing of mucous membranes of the vagina.

## General Information

### Bacterial Vaginosis

Vaginitis is a medical term used to describe various conditions that cause infection or inflammation of the vagina that can result in unpleasant odors, discharge, itching, dryness and burning.

Bacterial vaginosis, or BV, is the most common cause of abnormal vaginal discharge in women from puberty to menopause and is twice as common as yeast infections. Despite being common, it is still not clear what causes BV, and why some women get BV and others don't.

BV is the result of an overgrowth of certain bacteria in the vagina triggered by an imbalance of the vaginal pH. A normal and healthy vagina is naturally acidic with a low pH of approximately 3.8-4.5. This natural acidity is maintained by lactic acid producing bacteria known as lactobacilli (friendly bacteria). These bacteria flourish in an acidic environment and form an important part of the natural defences, acting as a barrier to infections.

When BV does occur, there are fewer lactobacilli (friendly bacteria), which usually keep the vagina relatively acidic while other anaerobic bacteria (unfriendly bacteria) proliferate, causing an increase in vaginal discharge and characteristic odour. This overgrowth can be prevented or eliminated by restoring and maintaining vaginal pH within its normal range of 3.8-4.5.

GYNALAC eliminates unpleasant vaginal odor and discharge by restoring and maintaining a women's delicate vaginal pH balance within its normal acidic range (pH of 3.8-4.5). Restoring the normal vaginal pH helps to prevent or inhibit overgrowth of pathogens, until such time as the lactobacilli have become re-established and can maintain vaginal pH unassisted.

GYNALAC provides an effective natural protection against infection and irritation, as the majority of harmful micro-organisms cannot survive at a low pH level.

### Symptoms of Bacterial Vaginosis:

Most women (50-75%) do not experience symptoms of BV, but when they do they typically have an abnormal vaginal discharge with an unpleasant odor. Some women report a strong fish-like odor, especially after intercourse. Discharge, if present, is usually white or gray and it can be thin. Women with BV may also have a burning sensation during urination or itching around the outside of the vagina, or both.

Symptoms of Bacterial Vaginosis include:

- Vaginal itching
- Vaginal burning sensation
- Vaginal irritation
- Painful urination
- Painful sexual intercourse
- Vaginal discharge, usually thin and grayish/white; discharge may be more noticeable after having sex\*
- Foul "fishy" odor\*

\*As the symptoms of both yeast infections and BV can be very similar, two out of three women frequently misdiagnose their symptoms and use the wrong treatment. One major recognizable difference between BV and Yeast infections is the bothersome unpleasant "fishy" odor associated with BV, especially after sexual intercourse.

It is important to distinguish between BV and Yeast infections as over-the-counter anti-fungal medications are not effective against BV. If you are unsure about your condition, consult your healthcare professional.

### Risk Factors that May Predispose Patients to Bacterial Vaginosis:

Any woman can get BV. However, some activities or behaviors can upset the normal balance of bacteria in the vagina and put women at increased risk including:

- Menstruation
- Contraceptives
- Douching

- Having a new sex partner or multiple sex partners
- Using antibiotics
- Using vaginal medications
- Smoking
- Stress
- Menopause
- Diet

### Tips on Maintaining Feminine Hygiene

- **Wear loose, breathable, bottom clothing.** Tight pants, shorts, or panties made from synthetic fabrics can reduce the air circulation around your vagina and cause it to sweat, which can increase your chances for odours and infection.
- **Remove wet, sweaty bottom clothing as soon as possible.** Wet or sweaty panties and pants can cause bacteria to multiply and increase your likelihood for getting odors and infections.
- **Wash your vaginal area daily with mild soap and water.** Rinse your vaginal region with fresh water after washing with soap, then dry off immediately with a clean, towel to prevent moisture build-up.
- **Wipe your genital area thoroughly after urination.** Wipe yourself from front to back after you experience a bowel movement to prevent fecal matter from coming into contact with your vagina, which can cause a bacterial infection.
- **Change tampons, sanitary napkins, and panty liners frequently.** When these menstrual products become soiled and are worn for long periods of time, they can cause you to experience foul odors and increase the risk of infection.
- **Wash your vaginal area after sexual intercourse.** Bodily fluids and residue from condoms and other intimate products can cause infection, irritation, and odors if not removed from your vaginal region following intercourse.
- **Eat a balanced diet high in nutrition.** A diet with plenty of fruits, vegetables, and whole grains will help prevent your body and vagina from experiencing infections or ailments.

### Composition:

GYNALAC contains lactic acid and sodium hyaluronate, both of which are normally produced by a women's body. These two natural ingredients are applied directly into a woman's

vagina and can help protect against odor and vaginal discomfort.

**Lactic acid** is naturally produced by a women's body and plays a role in the normal maintenance of the vaginal ecosystem by restoring the normal acidic pH balance of the vagina, thereby contributing to the reestablishment of the natural vaginal flora. Presence in adequate amounts ensures the maintenance of an acidic vaginal pH, where Lactobacilli can adequately proliferate and correctly metabolize to produce more lactic acid. Clinical evidence has demonstrated that a treatment course of lactic acid helps to relieve and prevent symptoms of bacterial vaginosis.

**Sodium hyaluronate** is also naturally produced by a woman's body. It can store extremely large quantities of water, forms a natural moisturizing liquid film, is responsible for the moisture and elasticity of the vaginal skin and protects the vaginal skin, thereby reducing irritation and preventing itching and burning.

**Glycogen** is found in many places in the body and is used by friendly vaginal bacteria, such as Lactobacilli, as an energy source during anaerobic metabolism to produce lactic acid. This production of endogenous lactic acid further supports positive vaginal health.

### Recommended Use:

GYNALAC helps relieve and prevent symptoms of bacterial vaginosis and non-specific vaginitis. Eliminates abnormal vaginal discharge and unpleasant odors. Restores normal pH balance of the vagina and normal vaginal flora by supporting the growth of endogenous protective Lactobacilli bacteria. Provides immediate relief of dryness, itching, pain, and burning associated with Bacterial Vaginosis and non-specific vaginitis.

### Precautions and Warnings:

Skin irritation (redness, burning, itch) may occur during vaginal fungal (yeast) infections or when there are small fissures in the vaginal tissue. Consult a health care practitioner if symptoms worsen or persist.

### Contraindications:

Individual hypersensitivity to any of the ingredients. Do not use GYNALAC you are trying to get pregnant as semen is alkaline and may be neutralized by lactic acid.

### Use in Pregnancy:

GYNALAC can be used during pregnancy and during breastfeeding. If a vaginal infection occurs

during pregnancy, consult a health care practitioner.

### Directions:

**Acute treatment:** For rapid relief of vaginal infection and symptoms such as embarrassing odor, abnormal discharge, and vaginal discomfort, administer a single application (3 mL) for 7 consecutive days (preferably at bedtime) directly into the vagina using the applicator.

### Maintenance and prevention or recurrence of symptoms around the menstrual cycle:

Administer a single application (3 mL) per day for 3 days immediately after the menstrual cycle, directly into the vagina using the applicator, for a minimum of 6 months.

**Maintaining normal pH level during a course of antibiotics:** Administer a single application (3 mL) daily for 3 days directly into the vagina after the end of antibiotic therapy.

### Instructions for Use:

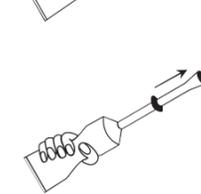
GYNALAC is inserted into the vagina using the enclosed applicator, which is filled with 3 mL of vaginal gel .

### Notes on Use:

Using the applicator is similar to inserting a tampon.



**Step 1:** Pierce tube with end cap and screw the applicator onto the opening of the tube.



**Step 2:** Pull the piston and fill up the applicator until the 3 mL stop line position by pressing the tube, to obtain one dose of GYNALAC vaginal gel.



**Step 3:** Unscrew the applicator from the tube, find a comfortable position and insert the applicator into the vagina. Gently push the piston to empty the complete dose of gel into the vagina.

It is recommended to apply a thin layer of the gel on the applicator's edge to facilitate the insertion of the applicator into the vagina.

### Caution:

- Do not ingest. This product is for vaginal application only.
- Ensure to wash your hands after each application.

- The device (gel and applicator) is intended for individual use and must not be shared.

### After use, clean the applicator thoroughly as follows:

- Dismantle the applicator by removing the piston.
- Wash with mild soap and lukewarm water: rub the applicator with fingers, fill and drain the cylinder repeatedly with water.
- Remove excess water by shaking the applicator and dry with a clean towel.
- Do not boil or use hot water.

### Storage Instructions:

Store GYNALAC vaginal gel in a dry place at room temperature, 15°C to 30°C. Do not use beyond the expiry date. The expiry date is stated on the tube and carton. Once used, the tube can be disposed of in accordance with local and environmental regulations.

**Medicinal ingredients:** Each application contains 225 mg of Lactic acid (DL-lactic acid), and 5 mg of Sodium hyaluronate

**Non-Medicinal ingredients:** Aqua/Water/Eau, Butylene Glycol, Glycogen, Hydroxyethylcellulose, Linum Usitatissimum (Linseed) Seed Extract, Potassium Sorbate, Rubus Coreanus Fruit Extract, Sodium Lactate, Sodium Levulinate, Tocopherol (Vitamin E)

### Paraben-free, Fragrance-free.

### Packaging:

Each box contains a 35 mL tube of product and one reusable plastic applicator.

**For more information, please visit our website: [www.GYNALAC.com](http://www.GYNALAC.com).**

### Manufactured & Distributed by:

Tyros Biopharma Inc.  
100 Alexis-Nihon Blvd., #219  
Montreal, Quebec H4M 2N7

Proudly made in Canada

Revision: October 2017