HYLAFEM BORICUM ACIDUM 2X- boricum acidum suppository
US Pharmaceutical Corporation

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

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hylafem™ Homeopathic Rx Vaginal Suppositories

PRESCRIBING INFORMATION

HYLAFEM VAGINAL SUPPOSITORIES contains the active ingredient, Boricum Acidum 2X in a Probiotic Blend base. Inactive Ingredients are Lactic Acid Bacteria, Lactobacillus casei KE-99 and Lactobacillus gasseri JPS, antioxidants, Vitamin C (Ascorbic Acid) and Vitamin E (as dl-Alpha Tocopheryl Acetate) and Maltodextrin.

Warning:
FOR VAGINAL USE ONLY. USE AS DIRECTED BY A PHYSICIAN. NOT TO BE TAKEN ORALLY.
KEEP OUT OF REACH OF CHILDREN. If accidentally swallowed, seek medical help or contact the Poison Control Center immediately.

INDICATIONS AND USAGE

Hylafem is a homeopathic prescription to
- Treat vaginal yeast infection.
- Rebalance vaginal pH and restore normal vaginal health.
- Help relieve symptoms of internal and external vaginal burning, itching, and irritation.
- Help reduce vaginal foul odor due to vaginal infection.

DOSAGE AND ADMINISTRATION
- For acute infection, insert into the vagina with an applicator one (1) capsule suppository a day for three (3) days or as prescribed by a physician.
- For chronic infection or related symptoms, insert into the vagina with an applicator one (1) capsule suppository a day for six (6) days or as prescribed by a physician.

DIRECTION FOR USE
- Wash hands thoroughly with soap and water
- Take out the capsule suppository from the foil pouch and insert the capsule suppository into the open end of the applicator.
- Lie on your back, draw your knees up a little and spread them apart.
- Gently insert the applicator with the capsule suppository into the vagina as far as possible.
- Depress the plunger so that the capsule suppository is released.
- Withdraw the applicator and discard the disposable applicator.
- Wear panty liner after each application.
CONTRAINDICATIONS
Before taking Hylafem, consult a doctor

- If you are pregnant or nursing. Boric acid should not be used in pregnant women due to the risk of teratogenic effects and the lack of data demonstrating safety. No data is available regarding the safety of boric acid in lactating mothers; therefore, it should not be recommended in this patient population.
- If you have any other health problems such as high blood pressure or heart or blood vessel disease.
- If you are an immune-compromised patient.
- If you have open wounds, vaginal bleeding, sores, ulcerations, nausea, fever or chills, sensitivity in your lower pelvis or abdomen, sexually transmitted disease (STD) or pelvic inflammatory disease (PID).

WARNINGS AND PRECAUTIONS
Stop use and consult a doctor

- If symptoms persist or reappear, or if you have high fever or a burning sensation or a worsening vaginal itch and discharge condition.
- If you experience an allergic reaction to any of its ingredients such as breathing problems or tightness in your throat or chest or chest pain or skin hives, rash or itchy or swollen skin.

ADVERSE REACTIONS AND SIDE EFFECTS
Hylafem’s ingredients are generally safe when used as directed, but there is no known information about the safety of its long-term use. Boricum Acidum 2X is equivalent to 0.025mg of Boric Acid per capsule. In most recent research, no serious side effects were reported when boric acid was used as a short course treatment for vaginitis.

The adverse effects are considered mild and may include watery discharge, erythema, or a slight burning sensation or a gritty sensation with intercourse during the treatment period.

Note: It is advised to avoid sexual intercourse during treatment period.

You should contact your healthcare provider for medical advice about adverse events. To report a serious adverse event, contact US Pharmaceutical Corporation, P. O. Box 360465 Decatur GA 30036 or at website: www.uspco.com.

DRUG INTERACTIONS
If you are taking other medications, consult a doctor before using this product. Although there are no known drug interactions with Boric Acid, it is advisable to consult a doctor when taking this product with -

Estrogens
Taking Boric Acid that is exceeding the prescribed dose with Estrogens can possibly increase the estrogen level in the body.

**Magnesium**

Taking Boric Acid that is exceeding the prescribed dose can lower the amount of Magnesium that is flushed out in the urine. This can lead to blood levels of Magnesium that are higher than usual.

**OVERDOSAGE AND TOXICITY**

The risk of systemic toxicity on Boric Acid depends on the concentration used, route of administration, age of the patient, skin condition, and duration of exposure. The fatal adult dose is about 20 grams or 0.1-0.5 mg/kg taken orally. The intravaginal administration of Boric Acid, 0.025 mg per suppository is safe to use and expected not to pose risk of systemic toxicity at the prescribed dosage.

**CLINICAL PHARMACOLOGY**

The rise in vaginal pH can increase the likelihood of vaginal infection.

Vaginal fluid acidity plays an important role in the maintenance of vaginal health. A women's normal vaginal fluid pH ranges between 3.8 and 4.5 which means the vagina is acidic, for which its acidity has been shown to be bactericidal. ¹

Hormone levels play an active role in balancing vaginal pH. Changing hormonal levels (during pregnancy, menopause and menstrual cycles), can influence the vaginal pH balance. At menopausal stage, estrogen levels decrease, which leads to the loss of vagina elasticity as well as thinning of the vaginal wall. It also leads to decrease in vaginal secretions and alters normal vaginal pH and vaginal flora. ¹,²

Other factors that may lead to vaginal Infection

Douching can change the necessary balance of vaginal flora that help to protect a woman from infection. Douching will only mask the vaginal odor for a short time and will make the problem worse. Douching can cause an overgrowth of harmful bacteria or yeast. If the infection exists, douching can push the harmful bacteria up into the uterus, fallopian tubes and ovaries and may lead to pelvic inflammatory disease.³

Use of tampons that absorb menstrual fluid for an extended period of time as well as its material may also lead to vaginal infection. Chemicals present in some tampons may also affect vaginal pH levels. Some women regularly experience vaginal infections following their periods for this reason.²

Scented tampons, pads, powders and feminine deodorant vaginal sprays may also increase the chance of getting vaginal infection.⁴

An elevated pH could occur for other reasons and a doctor should be consulted for further testing and treatment.

**Mechanism of Action**

**Hylafem**’s active ingredient, **Boricum Acidum 2X** in a Probiotic Blend base is an alternative homeopathic prescription remedy specially formulated to treat and relieve the symptoms of vaginal infections such as vaginal foul odor, burning, itching and irritation by restoring the normal vaginal acidity. It is a chemical substance with mild antiseptic, antifungal, and antiviral properties. A blend of lactic acid bacteria, *Lactobacillus casei KE-99* and *Lactobacillus gasseri JPS*, and anti-oxidants - Vitamin C and E are added to the inactive base to help keep a healthy and balanced vaginal flora. Hylafem ingredients are delivered in a quick-dissolving vegetable capsule.

Boricum Acidum (Boric acid) has fungistatic properties, but the exact mechanism of action is unknown. It is postulated that the fungistatic effects of Boric Acid may be the result of its inherent properties as a
weak acid. The acid penetrates the cell wall and disrupts the cell membrane of fungus and other pathogens by inhibiting the ergosterol synthesis.\(^5\)

Delivering Boricum Acidum 2X in a Probiotic base, Lactic Acid Bacteria such as *Lactobacillus casei* and *Lactobacillus gasseri*, which are considered natural parts of the vaginal flora, effectively protects the vagina against pathogens by producing antimicrobials such as hydrogen peroxide, bacteriocins, and weak organic acids like acetic and lactic acid. *Lactobacillus* spp. ferment glycogen secreted by vaginal epithelial cells into lactic acid, and colonization by these microorganisms correlates to the low pH in the vagina. The acidic environment protects the vagina against overgrowth of pathogens. Low vaginal pH is also beneficial for other antimicrobials; hydrogen peroxide (H\(_2\)O\(_2\)) is stable in this condition and bacteriocins are highly active. An increase of the vaginal pH leads to the decrease of the lactobacilli-associated antimicrobial activity.\(^6\)

**HOW SUPPLIED, STORAGE AND HANDLING**

Hylafem is supplied in white opaque vegetable capsules in individual foil packets of 3 capsules, NDC #52747-0250-03 with three (3) disposable vaginal applicators in each carton. Keep away from sunlight and store unopened packets in a cool, dry place at 15°C - 30°C.

**PATIENT COUNSELING INFORMATION**

**Important Note:** The above information is intended to supplement, not substitute for, the expertise and judgement of your doctor, pharmacist or other healthcare professional.

Patient is advised to avoid sexual intercourse when using this product to prevent further irritation or infection.

Hylafem is not to be used as a contraceptive or to prevent/treat sexually transmitted diseases.

**REFERENCES**

1. Just-Health.net, Vaginal pH Balance
2. Rotarangi, D., Vaginal pH – Everything You Need to Know
3. Womenshealth.gov, ePublications, Our ePublications, Douching Fact Sheet
4. Center for Young Women’s Health, Vaginal Infections (Vaginitis), 06/2014

**Rx Only**

*Boricum Acidum 2X in a Probiotic Blend Base*

Distributed by:

US Pharmaceutical Corporation
2443 Park Central Blvd
Decatur GA 30035, USA

**Packaging**
**Product Information**

**Product Type**
- HUMAN PRESCRIPTION DRUG

**Route of Administration**
- VAGINAL

**Item Code (Source)**
- NDC:52747-250

**Active Ingredient/Active Moiety**

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**Product Characteristics**

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*Note: The above information is a representation of the text content extracted from the image. It may be different from the original document format.*
Terra Botanica, LLC | 963736785 | manufacture(52747-250)

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US Pharmaceutical Corporation