

Gynatrof[®]

(Sodium Hyaluronate & Vitamin E)

Description

GYNATROF is a pH-balanced and isotonic vaginal gel designed to relieve the symptoms of vaginal atrophy such as dryness, burning, itching / irritation, urinary incontinence and painful sexual activity.

General Information

Vaginal atrophy is a treatable chronic condition that refers to the thinning of the vaginal wall. Symptoms of vaginal atrophy are common in women during their pre and postmenopausal years and are largely due to the decline in the level of the female hormone, estrogen. The decline in estrogen can lead to alterations in the vagina and can occur in the following situations:

- During or after menopause
- After childbirth
- While breast feeding
- When using hormone preparations (oral contraceptives)
- During chemotherapy

The decline in estrogen can greatly affect quality of life, even making sitting, standing, exercising or urinating uncomfortable. The earliest symptoms are decreased vaginal lubrication (dryness) and pain during sexual intercourse, followed by other vaginal and urinary symptoms that may be exacerbated by superimposed infection. Vaginal atrophy also can increase your risk of vaginal infections and urinary tract infections (UTIs).

Symptoms

As estrogen levels decrease, the vaginal walls become atrophic, dry and can cause vaginal discomfort.

Vaginal atrophy can lead to the following symptoms:

- Dryness
- Burning
- Itching
- Irritation
- Urinary continence
- Painful sexual activity
- Bleeding
- Recurrent urinary tract infections

Indication

Gynatrof helps relieve symptoms associated with vaginal atrophy, such as vaginal dryness, pain, itching, burning, urinary incontinence and painful sexual activity (dyspareunia). In menopausal women, Gynatrof helps relieve vaginal dryness and contributes to the maintenance of a healthy vaginal mucosa and pH and maturation of the vaginal epithelium.

Composition

GYNATROF contains sodium hyaluronate (hyaluronic acid), which is normally produced by a women's body. Hyaluronic acid is able to 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. Vitamin E is a natural antioxidant that helps prevent aging of the vaginal tissue and reduces inflammation. Lactic Acid restores the normal acidic pH balance of the vagina.

Ingredients

Aqua/Water, Sodium Hyaluronate, Tocopherol (Vit. E), Lactic Acid, Hydroxyethylcellulose, Sodium levulinate, Potassium sorbate, Polysorbate 20

Contraindications

Individual hypersensitivity to any of the ingredients.

Precautions and Warnings

Gynatrof is intended for vaginal use only and should not be ingested. Consult your healthcare professional before use if you

are pregnant or breast feeding. If symptoms worsen or persist, consult your healthcare professional. Gynatrof is compatible with non-lubricated latex, lubricated latex, lubricated polyisoprene and lubricated polyurethane male condoms.

Instructions for Use

Gynatrof is applied into the vagina and to the surrounding perivaginal area to relieve symptoms of vaginal atrophy.

Gynatrof is inserted into the vagina using the enclosed applicator, which is filled with 2.5 mL of vaginal gel (see "Notes on Use").

Initial therapy: The vaginal gel is administered once daily, for 7 consecutive days (preferably at bedtime).

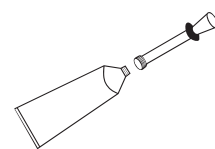
Maintenance therapy: Administer the vaginal gel 2 times weekly, every 3 days, or as needed.

Gynatrof can also be applied to the perivaginal area (the vaginal opening and external area) using fingertip. Perivaginal application can help to ease sexual activity and alleviate vulvar dryness. Apply gel as needed, for as long as you desire and to maintain a lasting effect.

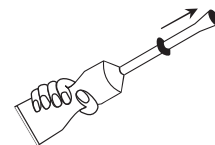
Notes on Use

Using the applicator is similar to inserting a tampon.

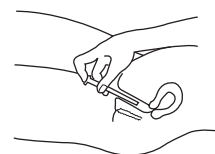
1. Remove foil and screw the applicator onto the opening of the tube.



2. Pull the piston and fill up the applicator until the 2.5 mL position by pressing the tube.



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



It is advisable to apply a thin layer of the gel on the applicators edge to facilitate the insertion of the applicator into the vagina.

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 until soap residue is removed.
- Remove excess water by shaking the applicator and dry with a clean towel.

Storage Instructions

Store the dismantled applicator in the original carton box and assemble it at next use. Store at room temperature.



Packaging: Vaginal applicator and tube should be disposed as plastic recyclable material. Carton box should be disposed as paper recyclable material.

For more information: www.gynatrof.com

Manufacturer:

TYROS BIOPHARMA INC. www.tyrosbiopharma.com

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