



- Dryness relief
- Intimate hygiene
- Improving of the vulvo-vaginal mucosa status
- Vaginal discomfort treatment and prevention:
 - Inflammation
 - Infection and itching
 - Irritation and burning

Medical Device



MADE IN ITALY

VAGINAL DISCOMFORT

DESCRIPTION

REVAGINAL vaginal douche formulation is based on hyaluronic acid and lactic acid. It is helpful in maintaining proper vulvovaginal mucosa status and proper acidity, washing gently vagina and preventing infections.



An irrigation per day or every two days, as needed

THERAPEUTIC INDICATIONS

- **Vulvovaginitis, characterized by:**
 - itching
 - burning
 - irritation
 - abnormal discharge
- **Alteration in vaginal pH**
- **Vaginal dryness**
- **Vulvar pain**

PRESENTATION

REVAGINAL vaginal douche is supplied in two different packages, containing:

- 4 bottles of 30mL and 4 disposable cannulas
- 1 bottle of 30mL and 1 disposable cannula

INGREDIENTS

Aqua, Sodium Hyaluronate, Lactic Acid, PVP, Disodium EDTA, Potassium Sorbate, Sodium Benzoate.

REGULATORY STATUS

- Class I *
- Free sale certificate
- Declaration of conformity
- Certificate of origin (at the time of invoicing)
- ISO 13485 certificate
- US FDA registration

*the product will be certified in class IIa within May 2020

PLUS

REVAGINAL vaginal douche permits a careful hygiene of vagina and helps to:

Restore the natural acidic protective layer of vagina



THANKS TO

Lactic acid

Restore normal epithelization and hydration



THANKS TO

Hyaluronic acid
(high and low molecular weight)



ACTION

Immediate correction of altered pH



Keeping of good and bad bacteria at their right levels

(making the intimate area safe from infection)



ACTION

Optimal adhesion to the vaginal mucosa, prolonged moisturizing action and promotion of natural processes.

CLINICAL TEST

RISK ANALYSIS - according to UNI CEI EN ISO 14971

BIOCOMPATIBILITY - according to UNI EN ISO 10993:

• **CYTOTOXICITY** for DIRECT CONTACT - according to EN ISO 10993-5:2009

• **VAGINAL MUCOSA IRRITATION TEST** - according to EN ISO 10993-10:2002

CLINICAL EVALUATION - according to MEDDEV 2.7-1

LONG TERM STABILITY STUDY - according to ICH Guidelines