



- Vaginal dryness
- Pain or discomfort during sex
- Prevention and control of vulvovaginitis

- Reduction of:
 - Vaginal itching
 - Burning
 - Irritation

Medical Device



MADE IN ITALY

VAGINAL DRYNESS

DESCRIPTION

Revaginal gel is useful in case of fungal and/or bacterial vaginosis, vaginal and vulvar dryness and in all situations in which is necessary a lenitive action giving relief to side effects related to a scarce vaginal lubrication as irritation, itching, burning, redness and hypersensitivity.

It can also be used in menopausal and in conjunction with estrogens and or progestin therapies (e.g. contraceptive pills and/or antibiotics).



It is recommended the application of gel once a day for 6 days.

THERAPEUTIC INDICATIONS

- **Vaginal dryness**
- **Vaginal atrophy**
- **Vaginal discharge/fluid reduction**
- **Itching, burning and irritation**

PRESENTATION

Revaginal Gel is available in two version:

Single-dose: Each box of Revaginal gel contains 6 disposable vaginal applicators of 5 mL.

Multidose: 30ml vaginal gel in multidose tube.

INGREDIENTS

Aqua, Hydroxyethylcellulose, Glycerin, Propylen glycol, Aloe Barbadensis, Ribes Nigrum extract, Lavandula angustifolia extract, Sodium hyaluronate, Peg 40 hydrogenated castor oil, Disodium edta, Chamomilla recutita extract, Calendula officinalis extract, Lactic acid, Arachidonic acid - Linoleic acid- Linolenic acid, Tocopheryl acetate, Retinylpalmitate, Imidazolidinyl urea, Potassium sorbate.

REGULATORY STATUS

- Class IIA
- Free sale certificate
- Certificate of origin (at the time of invoicing)
- ISO 13485 certificate

PLUS

Revaginal Gel Disposable it's ideal for:



Menopausal women



Young women with hormonal problems



Women with fungal or bacterial vaginosis (also in antifungal/antibacterial therapies)

Characteristics	Advantages	Benefits
Hyaluronic acid	Excellent moisturizing and lubricating action on vaginal mucosa	Reduces vaginal burning
Lactic acid	Rapid lowering action of vaginal pH	Restoration of natural vaginal defenses (vaginal flora)
pH 3.5	Restores of the physiological vaginal pH	Less infections
Disposable	Doses are precious	Simple and comfortable
Not cytotoxic Not irritant Not sensitizing	High tolerability	Woman Friendly

CLINICAL TEST

- **RISK ANALYSIS** - according to UNI CEI EN ISO 14971:2012
- **BIOCOMPATIBILITY** according to UNI EN ISO 10993:
- **CYTOTOXICITY** for DIRECT CONTACT - according to ISO 10993-5:2009
- **DELAYED HYPERSENSIVITY TEST (GPMT)** - according to ISO 10993-10:2010
- **VAGINAL IRRITATION TEST** - according to ISO 10993-10:2010
- **CLINICAL EVALUATION** – according to MEDDEV 2.7-1
- **STABILITY** - according to ICH Guidelines:
- **ACCELERATED STABILITY STUDY**

CLINICAL TRIAL



*Revaginal Gel:
Post-menopausal
vulvovaginal
disorders*

CLINICAL TRIAL ENDPOINTS



IRRITATION



BURNING



DRYNESS



DYSURIA



DYSPAREUNIA

PROSPECTIVE STUDY



20 Woman



**2 weeks of
Treatments**

EVALUATION OF POST MENOPAUSAL VULVOVAGINAL DISCOMFORT

Through
VSQ Questionnaire

RESULTS OF THE TRIAL

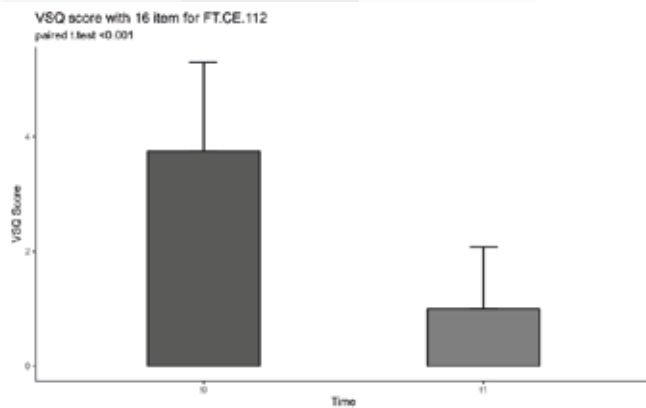


Figure 1. VSQ Questionnaire overall 16-item scores, before (T0) and after(T1) the treatment

Overall Evaluation of symptoms before and after treatment

After 2 weeks of treatments:

- ↓ Dryness (-50%)
- ↓ Burning (-80%)
- ↓ Irritation (-89%)
- ↓ Pain (-100%)
- ↓ Itching (-94 %)
- ↑ Intimate Desires (+60%)

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