
- Vaginal Dryness
- Inflammation
- Infection and itching
- Irritation and burning

Medical Device II CE 0426

PJ PHARMA

Quality Assurance ISO 9001 - ISO 13485

MADE IN ITALY

# INTIMATE DISCOMFORT

## DESCRIPTION

**Revaginal Ovules** are useful in preventing and treating non-specific vaginal dryness as well as atrophic vaginitis. Adjuvant in case of irritation, burning and vaginal discharge as well as in vaginal and flogic and infectious diseases. Suitable for women of childbearing age, menopause and perimenopause. The product is compatible with condoms.

**Dosing:** 1 suppository/day inserted in the vagina at bedtime for 5-7 consecutive days (away from the menstrual period).

## THERAPEUTIC INDICATIONS

- **Menopausal women**
- **Young women with hormonal problems**
- **Women with fungal or bacterial vaginitis** *(also in antifungal/antibacterial therapies)*

## PRESENTATION

Each pack of Revaginal ovules contains:
10 vaginal ovules of 2g in blister.

## INGREDIENTS

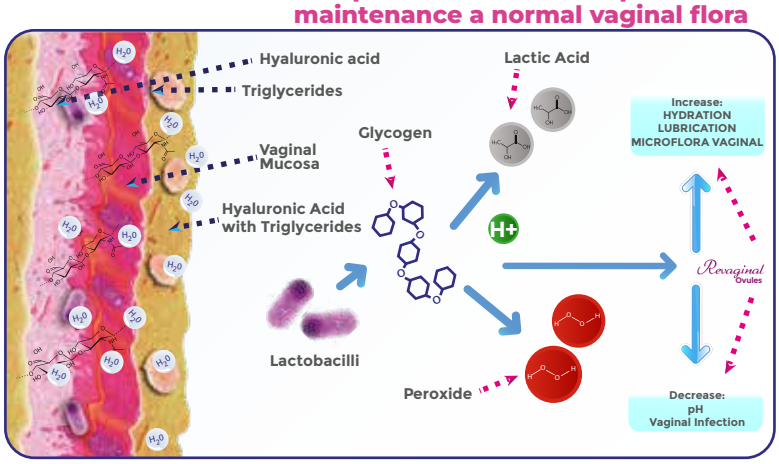
Medical device based on hyaluronic acid sodium salt, polycarbophil, lactic acid, Vitamin E, 18-beta-glycyrrhetinic acid, tea tree oil, phosphatidylcholine, semi-synthetic triglycerides.

## REGULATORY STATUS

- Class IIa
- Free sale certificate
- CE certificate
- Certificate of origin (at the time of invoicing)
- ISO 13485 certificate
- US FDA registration

## PLUS

### The importance of the acid pH for the maintenance a normal vaginal flora




| Characteristics | Advantages | Benefits |
|---|---|---|
| Hyaluronic acid | Excellent moisturizing and lubricating action on vaginal mucosa | Reduces vaginal burning |
| Triglycerides | Lubricating action | Relief and well-being |
| 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 |
| Policarbophil | Slow decrease of pH | Restoration of natural vaginal defenses (vaginal flora) |
| Long periods: Not cytotoxic Not irritant Not sensitizing | High tolerability | Woman Friendly |
| Condoms: Compatible with condoms | Intimate security | Woman Friendly |

**18-beta-glycyrrhetinic Acid and Vitamin E** → **Contribute to cellular integrity**

**Tea Tree Oil** → **Natural preservative**

## CLINICAL TEST

**RISK ANALYSIS - according to UNI CEI EN ISO 14971**
**BIOCOMPATIBILITY – according to UNI EN ISO 10993-1:2010**
- CYTOTOXICITY for DIRECT CONTACT - according to EN ISO 10993-5:1999 (UNI EN ISO 10993-5:2009)
- DELAYED HYPERENSIVITY TEST (GPMT) - according to EN ISO 10993-10:2002 (UNI EN ISO 10993-5:2010)

**COMPATIBILITY WITH CONDOMS - According to EN ISO 4074:2002**
**CLINICAL EVALUATION – according to MEDDEV 2.7-1 rev.4**
**STABILITY - according to ICH Guidelines and current F.U. and E.P. :**
- LONG TERM

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# CLINICAL TRIAL

## *Revaginal Ovules: Vulvovaginal and Uterine Regeneration*


## CLINICAL TRIAL ENDPOINTS

**IRRITATION**

**BURNING**

**DRYNESS**

**DYSURIA**

**DYSPAREUNIA**

## PROSPECTIVE STUDY

Sample Size Estimated Approved

**20 Woman**

**1 Ovules per day**

# EVALUATION OF POST MENOPAUSAL VULVOVAGINAL DISCOMFORT

*Through*

## VSQ Questionnaire

## RESULTS OF THE TRIAL

### Overall Evaluation of symptoms before and after treatment


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

*After 10 days of treatments:*

- Dryness (-90%)
- Burning (-100%)
- Irritation (-90%)
- Pain (-68%)
- Itching (-100 %)
- Intimate Desires (+64%)

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