



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

Medical Device II  0426



MADE IN ITALY

INTIMATE DISCOMFORT

PLUS

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 fungal 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.

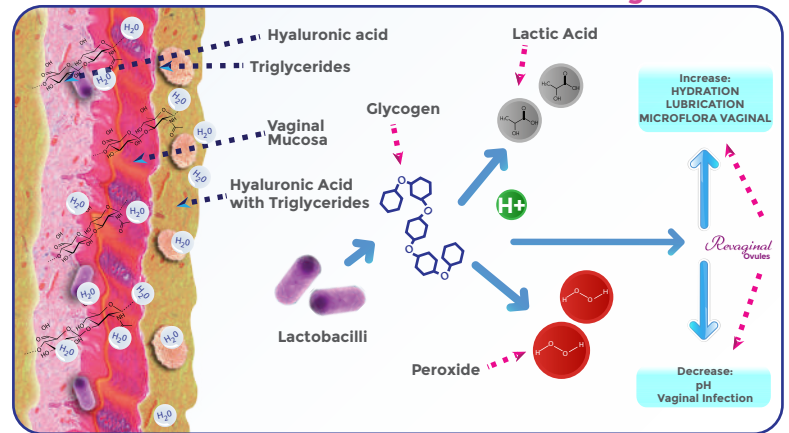
INGREDIENTS

Medical device based on hyaluronic acid sodium salt, polycarbophil, lactic acid, Vitamin E, 18-beta-glycyrrhetic 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



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
Polycarbophil	Slow decrease of pH	Restoration of natural vaginal defenses (vaginal flora)
 Not cytotoxic Not irritant Not sensitizing	High tolerability	Woman Friendly
 Compatible with condoms	Intimate security	Woman Friendly

18-beta-glycyrrhetic 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 HYPERSENSIVITY 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