



- Restoration of the Vaginal Flora
- Prevention and control of vulvovaginitis (even in case of mycosis)
- Reduction of vaginal itching, burning, and irritation.

Medical Device IIa  0426



MADE IN ITALY

MYCOTICVULVOVAGINITIS

DESCRIPTION

Lattawin ovules are vaginal suppositories based on Lactic Acid, Boric Acid and Polycarbophil helpful in restoring of natural pH of the vagina. The combined action of the components of Lattawin ovules restores the vaginal bacterial flora and reduces burning itchiness and irritation even in case of fungal infection. In case of risk of infection prevents the appearance of vaginal diseases.



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

THERAPEUTIC INDICATIONS

• Vulvovaginitis

- bacterial
- fungal
- caused by yeast infections

• In case of increased risk of infection

- Use of public restroom
- Exposure in swimming pools and gyms

PRESENTATION

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

INGREDIENTS

Boric acid, polycarbophil, lactic acid, tocopheryl acetate, 18-beta-glycyrhretinic acid, tea tree oil, phosphatidylcholine, semisynthetic triglycerides.

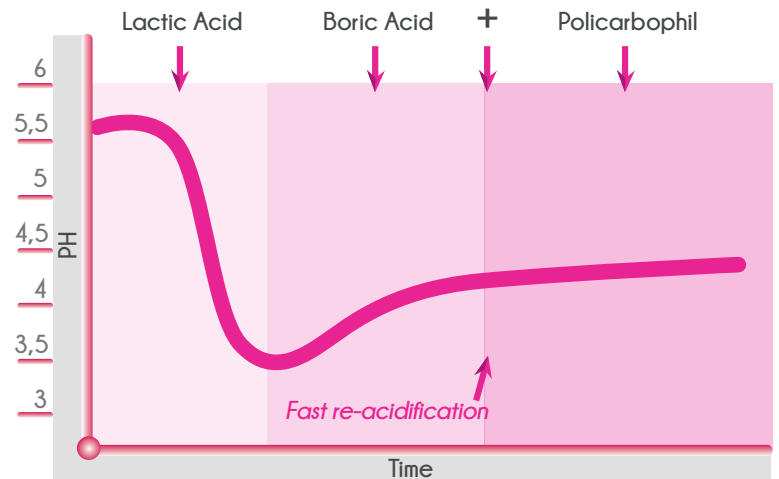
REGULATORY STATUS

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

PLUS

Vaginal flora and pH importance

	PH	LACTOBACILLI	SAPROPHYTIC	PATHOGENS
1	3,8 - 4,5	Minimum Decrease		
2	4 - 5	Moderate Decrease	Increase	
3	4,5 - 6	Important Decrease	Predominance	
4	> 4,5	Deficit of Production of Lactic Acid		Present
5	> 5	Reduced amount, unable to produce Lactic Acid	Poor	Present
6	> 5,5	Poor, ineffective	Absent	Present
7	6	Absence	Absent	Present
8-10	> 6	Absence	Absent	Abundant



IMMEDIATE ACTION

LACTIC ACID

Immediate correction of altered pH. H⁺ release permits the restoration of a pH=3.5-4 and of the natural defenses of the mucosa.

LONG-TERM ACTION

BORIC ACID

Shows acidifying action over time.

CONSTANT ACTION

POLYCARBOPHIL

It represents an H⁺ delivery system that releases H⁺ slowly and constantly.

18-beta-glycyrhretinic 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)

CLINICAL EVALUATION - according to MEDDEV 2.7-1 rev.4

STABILITY - according to ICH Guidelines and current F.U. and E.P. :

• LONG TERM

CLINICAL TRIAL

*Lattawin Ovules:
Clinical Relief for Vaginal
Affections*



CLINICAL TRIAL ENDPOINTS



**VAGINAL AFFECTIONS
ALSO MYCOTIC**



IRRITATION



BURNING



PAIN

PROSPECTIVE STUDY



20 Woman



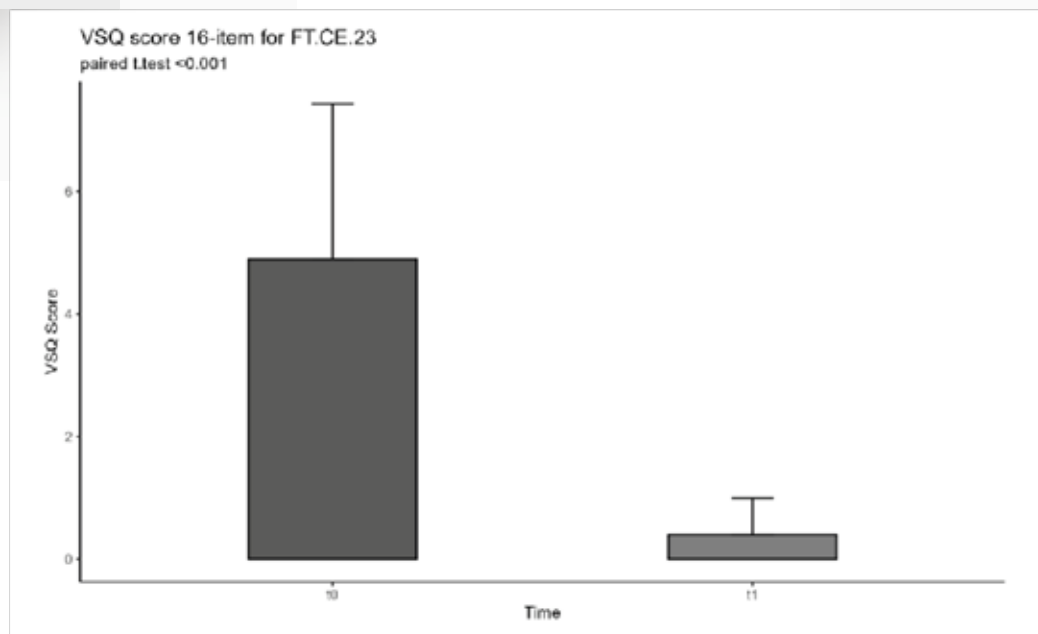
**1 Ovules
per day**

EVALUATION OF VAGINAL AFFECTIONS

Through
VSQ Questionnaire

RESULTS OF THE TRIAL

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



After 10 days of treatments:

- Dryness (-100%)
- Burning (-94%)
- Irritation (-100%)
- Pain (-91%)
- Itching (-92%)
- Intimate Desires (+100%)

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