



- Vaginal Dryness
- Irritation
- Inflammation

- Vaginal infections
- Burning and itching

Medical Device CE 0426



MADE IN ITALY

MYCOTICVULVOVAGINITIS



DESCRIPTION

Caregyn ovules are vaginal ovules based on Hyaluronic Acid, Boric Acid and Lactic Acid indicated in the flogistic and infective affections of the vagina, prevention and treatment of vaginal dryness, in case of vaginal irritation (vaginitis, bacterial vaginosis), burning and itching.



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

THERAPEUTIC INDICATIONS

- Vulvo vaginitis
- Vaginal infections (also in mycotic character)
- Bacterial vaginosis
- Vaginal Dryness

PRESENTATION

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

INGREDIENTS

Boric Acid, Hyaluronic Acid Sodium Salt, Polycarbophyl, Lactic Acid, Tocopheryl Acetate, Vitamin A, 18-beta-glycyrrhetic Acid, Tea Tree Oil, Semisynthetic Triglycerides. Phosphatidylcholine.

REGULATORY STATUS

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

Caregyn

Action of the components:

LACTIC ACID/BORIC ACID

Immediate Action
Lowering pH

Protection against pathogens

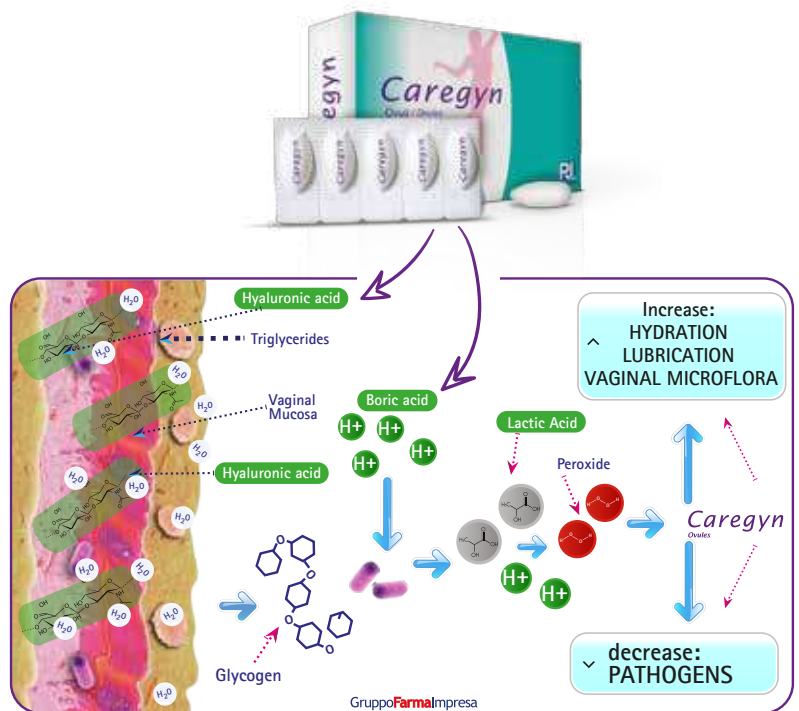
POLYCARBOPHYL

Constant Action
Lowering pH

HYALURONIC ACID

Moisturizing and
lubricating action

THE IMPROTANCE OF THE ACID pH FOR THE MAINTENANCE OF A NORMAL VAGINAL FLORA



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.:

