INSTRUCTIONS FOR THE USER

Qualitative and quantitative composition:
An ovule contains: bismuth subgallate – 100 mg, vegetable collagen – 15 mg, thyme extract (*Thymus vulgaris*) – 10 mg, goldenseal extract (*Hydrastis canadensis*) – 10 mg, calendula extract (*Calendula officinalis*) – 10 mg, turmeric extract (*Curcuma longa*) – 10 mg, hexylresorcinol – 2 mg, semisynthetic glycerides, anhydrous lanolin, colloidal silicon dioxide.

Aspect of the device:
Homogeneous ovules, yellow to dark yellow, without undissolved particles or air bubbles.
Each box contains 2 blisters with 5 ovules. The weight of an ovule is 2 g.

Intended users:
Cerviron is indicated for adult women (including women at menopause).

What it is used for:
Cerviron is used for the treatment of:
- acute and chronic vulvovaginitis of atrophic, aerobic, traumatic and infectious etiology,
- cervical erosions,
- vaginal bleedings of traumatic origin,
- disruption of vaginal pH and normal vaginal flora.

It can also be used for postoperative recovery after gynecological surgery and as an adjuvant in the treatment with antibiotics or antifungals.

Indications:
Cerviron is a medical device intended for use in the treatment of acute and chronic vulvovaginitis of atrophic, aerobic, traumatic and infectious etiology, of cervical erosions of traumatic or infectious origin and of bleedings caused by them, in the postoperative recovery after gynecological surgeries, for restoration of pH and normal vaginal flora, as well as an adjuvant in the treatment with antibiotics or antifungals.

Cerviron is indicated for the treatment of the following symptoms:
- vaginal pruritus,
- burning sensations in the vaginal area,
- rash,
- vaginal discharge with an unpleasant odour,
- dyspareunia,
- dysuria,
- vaginal bleedings caused by erosions of the cervix.

Cerviron can be used alone or in combination with a specific drug treatment for gynecological affections.

Contraindications:
Do not use Cerviron in case of hypersensitivity to any of the components of the product.

Pregnancy and breastfeeding
Due to the absence of sufficient clinical data, the administration of Cerviron to pregnant women cannot be recommended.
It is recommended to consult a specialist in this case. No precautions need to be taken when used during breastfeeding.

Effects on ability to drive and use machines
None of the components of the product affect the ability to drive or use machines.

Interactions with other products:
Interactions with other products are not known, therefore it is recommended to consult a doctor before using Cerviron together with other medical devices or medicines for vaginal use.

Dosage and administration:
An ovule is administered intravaginally, preferably in the evening before going to bed or according to the medical prescription.
Remove one shell from the blister by tearing along the perforated line. Then open the shell by slowly pulling apart the two layers at the end where they are not sealed together. Push from the other end to get the ovule out.
It is preferable to insert the ovule lying down.
Insert the ovule as deep as possible inside the vagina.
The use of ovules begins on the first day after menstruation. The duration of administration is 10 or 15 days per month, or according to the doctor's instructions. The effects can appear after the first month of treatment.
Usage can be repeated for several months until healing, or to consolidate and maintain the favourable effects obtained.

Special warnings and precautions for use:
- Due to the composition of the product, no precautions are generally required.
- Thoroughly sanitize your hands and intimate area before administering the ovule.
- Do not use ovules with damaged alveoli or traces of substance on the outside of the alveoli.
- Do not use ovules that are uneven in appearance or that show traces of agglomerated particles.
- Do not divide the ovules.
- Keep out of reach and sight of children.
- The product is for vaginal use. Do not swallow.
- Avoid contact with the eyes.
- Do not use the product after the expiry date indicated on the package and blister.
- Using the medical device can affect the effectiveness of condoms and latex diaphragms.
- Inform your doctor if you are planning a pregnancy.
- Inform the manufacturer or the competent authorities of any serious incident related to the use of the Cerviron medical device.

Side effects:
Using topical products for a long time may cause local irritation and sensitization. If side effects occur, stop treatment and contact your doctor or pharmacist.
Any serious incident that occurred in relation to the medical device must be reported to the manufacturer and the competent authority of the Member State where the patient is established.

Overdose:
No cases of overdose are known. The substances contained are not absorbed systemically, they are naturally eliminated in maximum 24 hours after administration.

Expiration, storage and disposal:
Store at 2 - 25 °C in the original package in order to protect from direct sunlight. The expiration date indicated on the package refers to the product stored under the conditions provided by the manufacturer. The medical device should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medical devices that you no longer use.

Manufacturer:
Perfect Care Manufacturing S.R.L.
no. 82 Complexului street,
085200 Mihailesti city,
Giurgiu county, Romania.
https://www.perfectcare.ro
contact@perfectcare.ro

Edition 03 Revision 01
Date of issue: 16.06.2025

CE 1282 MD