

HydroVag (logotype x2)

VAGINAL PESSARIES

PRODUCT DESCRIPTION

HydroVag vaginal pessaries moisturize the vaginal mucosa, contribute to mucosal regeneration, help to maintain natural pH level and protect the vagina against adverse external factors.

COMPOSITION

1 vaginal pessary contains: **10 mg of sodium hyaluronate, glycogen, lactic acid** and excipients: sodium lactate and semi-synthetic glycerides.

GENERAL INFORMATION

Vaginal epithelium maintains the proper moisture and pH level in the vagina. This state can be disrupted:

- by oestrogen deficiency, among others in natural menopause or in menopause caused by medical conditions (removal of uterus together with uterine adnexa),
- in long-term hormonal therapies (among others gonadoliberin (GnRH) agonists, glucocorticosteroids intake),
- in exposure to stress,
- after chemotherapy, radiotherapy.

The most common symptoms of vaginal epithelial dysfunctions, including vaginal atrophy, are: dryness, burning, itching, discomfort and painful sexual intercourse (dyspareunia).

ACTION

HydroVag pessary melts after placing into vagina and form a film covering the mucosa, which helps to restore the natural conditions of the vaginal epithelium. Sodium hyaluronate protects and moisturizes vaginal mucosa, contributes to tissue healing and regeneration. Lactic acid helps to maintain natural pH level in the vagina ($\text{pH} \leq 4.5$) to reduce the risk of infections. Glycogen provides a protective barrier and is a source of nutrients for lactic acid bacteria, which constitute the healthy vaginal microflora, protecting vagina from infections and helping to maintain the natural pH level.

Indications for use of HydroVag:

To alleviate **dryness and discomfort (tension, itching, burning sensation)** in the intimate areas caused by:

- oestrogen deficiency (during perimenopausal period, etc.),
- atrophy of the vaginal mucosa,
- increased stress.

In order to **support regeneration process of vaginal mucosa:**

- during perimenopausal period, in case of vaginal epithelium atrophy,
- in vaginal epithelium dystrophy caused by e.g. hormonal drugs (among others gonadoliberin GnRH agonists, glucocorticosteroids),
- after chemotherapy, radiotherapy,
- after gynaecological procedures (e.g. colposcopy, electrocoagulation, cryoablation and surgeries, for example episiotomy),
- after childbirth.

To alleviate pain in case of a **painful sexual intercourse** (dyspareunia).

To reduce the discomfort arising from **swelling, redness, and itching** in the vulval area as well as abnormal vaginal discharge.

As an adjuvant therapy to **maintain the normal microflora and pH level in the vagina**, e.g. after antibiotic therapy.

POSOLOGY

Basic therapy:

1 vaginal pessary in the evening before bedtime for 7 subsequent days or as recommended by a doctor.

Maintenance therapy:

1 vaginal pessary in the evening before bedtime every 2–3 days until permanent improvement in health or as recommended by a doctor.

If the maintenance therapy follows the basic therapy, the total duration of therapy cannot exceed 30 days. Afterwards, the treatment should be suspended for 7 days.

Do not take a double dose to make up for forgotten individual dose. Do not use two doses of the product simultaneously or at short time intervals.

INSTRUCTIONS FOR USE

1. Thoroughly wash your hands.
2. If the pessary appears too soft after exposing to high temperatures, place it in a refrigerator for a few minutes, before taking off the foil.
3. Tear off one item from a blister, slowly separate two film layers, peel them apart and carefully take out the pessary.
4. Gently insert the pessary deep into the vagina. The pessary can be moisturized in warm boiled water for easier application.

WARNINGS

- do not use the product if you are hypersensitive to any of the ingredients of the product,
- in the case of acute vaginal infections it is recommended to take the pessaries under medical supervision,
- due to the lack of studies pregnant or breast-feeding women can use the product only under medical supervision,
- do not use concomitantly with other vaginal preparations,
- the product used with topical anaesthetics may prolong the duration of anaesthesia as it contains sodium hyaluronate,
- do not use during menstrual bleeding,
- do not have sexual intercourse directly after the pessary application,
- do not use with condoms or vaginal contraceptive inserts made of latex as the product contains modified fats,
- do not use after expiry of the shelf-life stated on the packaging,
- do not use if the blister is damaged,
- do not swallow,
- keep out of sight and reach of children.

If any adverse reactions occur after the pessary is used (intensified itching, burning, rash, etc.) discontinue the therapy and consult your doctor.

To avoid underwear staining during the treatment, wear hygiene inserts.

Each pessary can be used only once. Repeated use of the same pessary carries the risk of vaginal contamination.

CONTENT OF THE PACK

HydroVag is available in packs containing 7 or 14 pessaries.

Not all pack sizes may be marketed.

STORAGE CONDITIONS

Keep in a tightly closed packaging at room temperature (15–25°C), in a dry place. Protect from light and high temperatures.



SHELF-LIFE

3 years

MEDICAL DEVICE



MANUFACTURER

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IBSS BIOMED S.A. (LOGO)

(Pharma Code)

						
<i>Manufacturer</i>	<i>Expiry date</i>	<i>Batch number</i>	<i>Read the instructions for use</i>	<i>Non-sterile</i>	<i>For single use only</i>	<i>Reccomended storage temperature</i>

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