

Before using the product, read the instructions for use, as they contain important information for the patient regarding the use of the product.

Keep the instructions for use so that you can read them again if necessary.

Vaginal suppositories 4/ WM Lideal/2016

DESCRIPTION OF THE MEDICAL DEVICE

The medical device *Vaginal suppositories 4/ WM Lideal/2016* creates a protective barrier on the surface of the mucous membrane, which moisturises and protects the vaginal mucosa from epithelial damage caused by vaginal dryness during intercourse, gynaecological examinations or physical activity. The use of this medical device improves vaginal elasticity, maintains and restores the physiological pH of the vagina, which helps to maintain the normal bacterial flora in the vagina and reduces unpleasant odours.

After application, the medical device forms a protective layer with an acidic pH, which helps to restore the natural physiological environment of the vagina, thus maintaining the normal microbiome of the entire female reproductive system (the microbiome is the entire set of microorganisms, including bacteria, that live in the host and regulate a number of physiological functions). Therefore, the medical device can be used to treat bacterial vaginosis (BV) and as a supplement to therapies used in the prevention and treatment of endometriosis.

Under normal conditions, the pH of the vagina is around 3.8-4.5, which promotes the growth of beneficial bacteria such as *Lactobacillus*, which inhibit the growth of pathogenic bacteria such as:

- *Gardnerella vaginalis*
- *Streptococcus* sp., *Enterococcus* sp., *E. coli*, *Enterobacter*, *Trichomona*
- *Candida* fungi

The product can be safely used by non-professional users at home.

The product is intended for women of childbearing age, as well as those in and after menopause.

COMPOSITION

1 globule contains: Sodium hyaluronate, Glycogen, Lactic acid, Tocopheryl acetate, Sodium lactate, Witepsol S58

Ingredients responsible for the essential action of the product

Sodium salt of hyaluronic acid – 10 mg / globule

GENERAL INFORMATION AND INDICATIONS

Indications for use of the medical device 4/WM Lideal/2016 Vaginal suppositories

- prevention of adverse changes in the vaginal flora and pH (e.g. travel, swimming pool, sauna, fitness, antibiotic therapy) by moisturising and maintaining the natural pH of the vagina;
- relief of symptoms of vaginal dryness (discomfort, tension, itching, burning of the vaginal mucosa) associated with:
 - atrophy of the vaginal mucosa
 - oestrogen deficiency
 - dyspareunia (painful intercourse)
 - prolonged stress;
- for additional lubrication of the vaginal epithelium:
 - after surgical and gynaecological procedures, after abrasions and other minor mechanical injuries to the vaginal mucosa
 - after childbirth
 - after chemotherapy, radiotherapy, cryotherapy
 - after laser procedures
 - for changes caused by the use of hormonal medications
 - during perimenopause;

- to reduce unpleasant vaginal odour associated with abnormal vaginal pH due to disturbances in the natural vaginal microflora,
- in the treatment of bacterial vaginosis (BV),
- to supplement therapies used in the treatment and prevention of endometriosis.

Non-hormonal product

Does not contain PEG, parabens, detergents, including: SLS, SLES

MECHANISM OF ACTION

The product acts at the site of application through a physical mechanism.

After applying vaginally, a moisturising protective layer is formed on the mucous membrane, which protects the vaginal epithelium from mechanical damage and reduces discomfort associated with dryness, tension, itching and burning of the vaginal mucosa.

The protective layer has an acidic pH, which contributes to the normalisation of the vaginal pH and the microbiome of the entire female reproductive system. Lactic acid and glycogen are responsible for the acidic pH of the product at the application site.

HOW TO USE

Note:

1. Wash your hands thoroughly before applying the product.
2. Remove 1 suppository from the blister pack by tearing the foil along the perforation and opening the foil wings.
3. Insert the ovule deep into the vagina.

Note: If the suppository is too soft, place it in the refrigerator for a few minutes before removing it from the foil until it hardens.

Unless otherwise prescribed by your doctor, use 1 suppository per night for 7 consecutive days. Then, to maintain the effect, take 1 suppository every 2-3 days until the symptoms disappear. Do not use the product for more than 30 days.

If your doctor recommends a different method of use than the one described above, follow your doctor's instructions.

If you miss a dose, do not use a double dose.

This product is for vaginal use only!

The product is intended for single-dose, single-use as one globule.

Insert the suppository immediately after removing it from the blister pack. A suppository removed from the blister pack cannot be used at a later time. This is inconsistent with the guidelines for use and storage of the product and may carry a risk of infection at the application site due to loss of product stability as a result of inconsistent storage conditions.

WARNINGS AND CONTRAINDICATIONS

- Hypersensitivity to the product components / occurrence of adverse reactions after use of the product:
 - Do not use the product if you are hypersensitive (allergic) to any of its ingredients.
 - If the patient has no known hypersensitivity to the ingredients of the product and during use of the gel a burning sensation, itching or redness appears which does not subside spontaneously, this may indicate hypersensitivity to the ingredients of the product, in which case you should discontinue use of the product and consult your doctor or pharmacist.
 - When using the product in cases of severe vaginal dryness, due to the lactic acid content of the product, slight reactions may occur at the site of application (mild burning or itching). These symptoms are temporary and usually disappear spontaneously. If the symptoms persist, this may indicate hypersensitivity to the ingredients of the product. In this case, discontinue use and consult your doctor or pharmacist.
- Do not use with local anaesthetics or other vaginal preparations, as the product may weaken or delay their action.
- Do not use with latex condoms or contraceptive inserts, as the product may reduce their effectiveness due to its fat content.

- Do not have sexual intercourse immediately after applying the suppository.
- During pregnancy and breastfeeding, use after consulting your doctor or pharmacist.
- In case of acute vaginal infection, use only after consulting a doctor.
- The product can be used with other vaginal products if recommended by a doctor.
- Do not use during menstruation.
- Avoid accidental contact of the product with the mucous membranes of the eyes, nose or mouth.
- The product is intended for vaginal use only.
- Do not use after the expiry date.
- Do not use the product if the blister pack is damaged.
- Do not reuse a suppository once it has been inserted.
- If the entire dose of the product is not used, the product should be disposed of. Do not attempt to reuse an opened product at a later date. This is contrary to the guidelines for use and storage of the product and may carry a risk of infection at the application site due to loss of product stability as a result of improper storage conditions.

STORAGE

Store at 15°C -25°C.

Store in the original packaging.

Protect from light and heat sources.

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the packaging.

Do not use if the packaging is damaged.

Empty containers, unused or expired products should be disposed of (recycled) in accordance with applicable regulations. This medical device does not contain any substances harmful to the environment.

Available product packaging:

Single-use product

Blister pack of 1 globule (free sample) in a single carton with instructions for use

Blister pack of 2 globules (free sample) in an individual cardboard box with instructions for use

Blister pack of 5 globules in an individual carton with instructions for use

Blister pack of 6 globules in an individual carton with instructions for use

Blister pack of 7 globules in an individual carton with instructions for use

2 x blister packs of 5 globules = 10 globules in a single carton with instructions for use

3 x blister packs of 5 globules = 15 globules in a single carton with instructions for use

Weight of one globule approx. 1.6 g



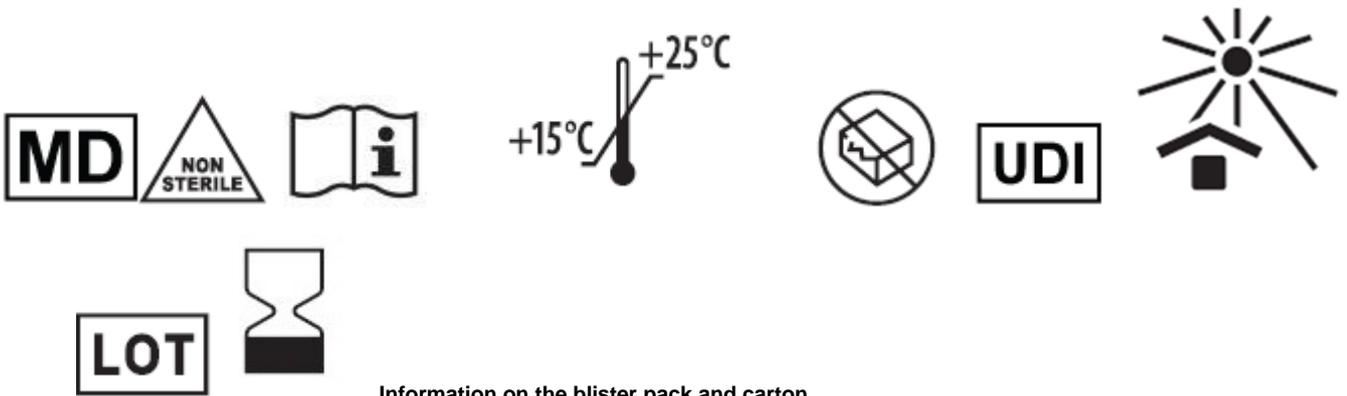
MANUFACTURER

CE 2274

Medical device

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DISTRIBUTOR



Information on the blister pack and carton

Adverse reactions and serious incidents related to the use of the medical device should be reported to the manufacturer or distributor and to the competent state authority.

Date of preparation of the instructions for use: Edition C of

Symbols and markings used

	Medical device
	Manufacturer
	Distributor
	Marking of conformity of the device with the MDR together with the identification number of the Notified Body involved in the conformity assessment of the product

	Use by date
	Batch number
	Non-sterile
	Permissible temperature range
	Single-use product
	Unique device identifier
	Do not use if the packaging is damaged
	Read the instructions for use
	Keep away from direct sunlight