

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 gel 1/ WM Lideal/2016

### DESCRIPTION OF THE MEDICAL DEVICE

The medical device Vaginal Gel 1/ WM Lideal/2016 is a high-quality gel that forms a protective layer 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.

The medical device has an acidic pH and helps to restore the natural, physiological environment of the vagina, which translates into maintaining the proper 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 to prevent and treat 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
- fungi of the genus Candida

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 applicator contains: sodium hyaluronate, lactic acid, glycerol, propylene glycol, hydroxyethylcellulose, phenoxyethanol, ethylhexylglycerin, purified water.

Ingredients responsible for the essential action of the product

Sodium hyaluronate - 0.01%

Hydroxyethylcellulose - 1.7%

Glycerol 85% - 4.0%

Propylene glycol – 3.0%

Purified water – 90.29%

### GENERAL INFORMATION AND INDICATIONS

Indications for use of the medical device Vaginal gel 1 / WM Lideal / 2016

- 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;
  - for additional vaginal lubrication, which helps to reduce discomfort during intercourse;
  - to reduce unpleasant vaginal odour associated with abnormal vaginal pH due to disturbances in the natural vaginal microflora,
  - for the treatment of bacterial vaginosis (BV),
  - to supplement therapies used in the treatment and prevention of endometriosis.

The product is easy and hygienic to apply, ensuring a high level of comfort.

Odourless

Non-hormonal product

Hypoallergenic product

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

## **MECHANISM OF ACTION**

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

After vaginal application, a moisturising protective layer is formed on the vaginal mucosa, 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.

## **HOW TO USE**

Note: Wash your hands thoroughly before applying the gel!

Then:

1. Remove the applicator cap.
2. Insert the applicator neck into the vagina.
3. Squeeze the entire contents of the applicator into the vagina.
4. Remove the applicator.
5. Discard the used applicator. Do not reuse the same applicator!

Use the product immediately after opening the applicator.

Unless otherwise prescribed by your doctor, use the contents of one applicator per night for 7 consecutive days. Then, to maintain the effect of the product, it is recommended to use one applicator every 2-3 days until the symptoms disappear. Do not use the product for more than 30 days.

If your doctor prescribes 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 of gel. If symptoms persist, consult your doctor or pharmacist about further use of the product.

You can also use 1 dose of the product immediately before intercourse.

The product is intended for vaginal use only.

The product is intended for use in disposable applicators and contains a single dose for single use .

If the entire dose of the product is not used, the applicator should be disposed of . Do not attempt to reuse an opened product at a later date. 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 improper storage conditions .

## **WARNINGS AND CONTRAINDICATIONS**

- Hypersensitivity to the product ingredients / 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 the use of the product should be discontinued and a doctor or pharmacist consulted.
    - 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.
- During pregnancy and breastfeeding, use only after consulting a doctor or pharmacist.
- Do not use when trying to conceive, as the pH of the gel has an adverse effect on sperm.
- Do not use during menstruation.
- If vaginal dryness persists, consult your doctor or pharmacist.
- Avoid accidental contact of the gel with the mucous membranes of the eyes, nose or mouth.
- Do not use with local anaesthetics and other vaginal preparations, including vaginal contraceptive preparations, as the product may weaken their effect.
- Do not use the product if the applicator is damaged.
- Do not reuse an applicator once it has been opened.
- Do not use after the expiry date.
- If the entire dose of the product has not been used, the applicator 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.
- Use the product immediately after dispensing the dose from the packaging, i.e. from the tube. The dispensed product cannot be used at a later time.
- The tube is a single-use dose; any unused amount should be disposed of in accordance with applicable regulations.
  
- The product is intended for vaginal use only. Do not swallow!

## **STORAGE**

Store the product in its original packaging.

Store at room temperature, i.e. 15-25 °C.

Protect from light and heat sources.

Keep out of the reach and sight of children.

Do not use the product if the immediate packaging is damaged.

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

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

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.

**The product packaging contains: disposable gel applicators with instructions for use.**

3 applicators (tubes) in a single carton with instructions for use

5 applicators (tubes) in a single carton with instructions for use

6 applicators (tubes) in a single carton with instructions for use

7 applicators (tubes) in a single carton with instructions for use

10 applicators (tubes) in a single box with instructions for use

free sample 1 applicator (tube) in a single carton with instructions for use

free sample 2 applicators (tubes) in a single box with instructions for use



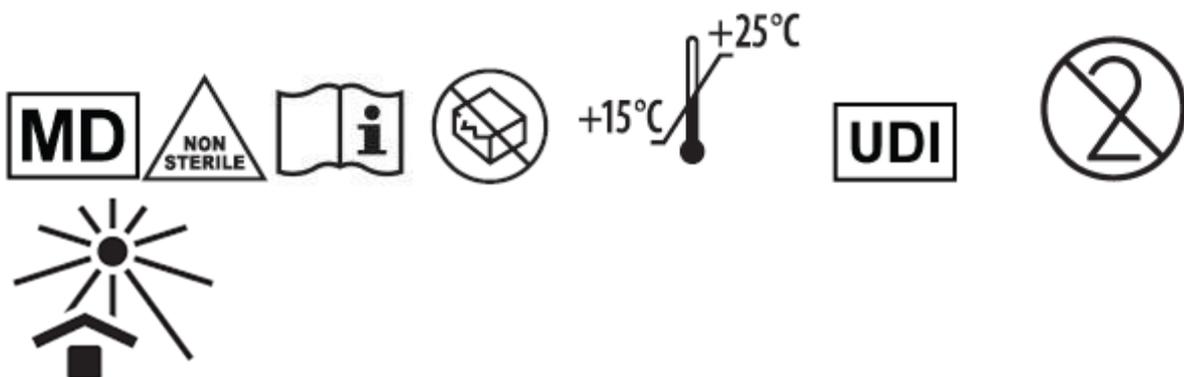
**MANUFACTURER**

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2274 Medical device

**DISTRIBUTOR**



**LOT**



Information on the packaging

Date of instruction update Edition C dated ...

### 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 exposure