

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.

MEDCARE Rectal suppositories with sodium hyaluronate

DESCRIPTION OF THE MEDICAL DEVICE

MEDCARE Sodium Hyaluronate Rectal Suppositories are a medical device with a moisturising and protective effect on the mucous membrane of the anus and rectum. It is recommended for rectal repair processes, e.g. in the case of haemorrhoids and anal fissures. It soothes and accelerates the healing of injuries resulting from surgical treatment of haemorrhoids and anal fissures. Through its protective and moisturising action, the product soothes inflammation of the anus and rectum, providing relief from persistent itching, stinging and burning of the anus and its surroundings, i.e. the perianal skin. It is also effective in preventing damage to the anus and rectum. The medical device can be used in cases of damage to the mucous membrane of the anus and rectum, commonly referred to as anal mucositis, resulting from chemotherapy, radiotherapy or a combination of both therapies. The medical device can be used in cases of irritation of the anus and rectum resulting from surgical treatment, diagnostic tests and in cases of irritation after anal penetration.

The medical device alleviates discomfort associated with damage to the mucous membrane of the anus and rectum, creating conditions conducive to the natural healing and regeneration process in cases of irritation and damage to the anus and rectum.

The product has a protective and moisturising effect on the mucous

membrane of the anus/rectum. The product is intended for lay use.

COMPOSITION

Composition: Sodium hyaluronate, Witepsol S58

Product form: The product is in the form of a rectal suppository; suppository weight 2 g; each suppository contains 10.6 mg sodium hyaluronate, which is responsible for the essential action of the medical device. One suppository is a single dose of the medical device

Ingredients responsible for the essential action of the product

Sodium hyaluronate 0.53%

MECHANISM OF ACTION OF THE PRODUCT

The product acts at the site of application.

After application of the product, the suppository melts and forms a moisturising protective layer.

The product works by a physical mechanism - it forms a protective layer on the surface of the rectal and anal mucosa, which allows the medical objective to be achieved.

The product remains on the mucous membrane of the anus and rectum until the first defecation after application of the suppository.

The product is removed from the application site during defecation and when washing the perianal area.

HOW TO USE:

Wash your hands before using the product!

Carefully remove 1 suppository from the packaging.

Insert the suppository into the rectum. It is not necessary to lie down during application. Unless otherwise recommended by your doctor, use 1 suppository before going to bed.

If you miss a dose, do not use a double dose, i.e. 2 suppositories. The product is intended for rectal use only.

Medical device for rectal use in adults.

Pregnant and breastfeeding women may use the product after consulting a doctor and under the direct supervision of the doctor supervising the pregnancy.

INDICATIONS

The product can be used in a 20-day treatment for the following indications:

- in haemorrhoidal disease with internal and external haemorrhoids; accompanied by acute or chronic inflammation, pain, itching
- in inflammation of the anus
- in cryptitis, fissures and anal fissures
- in perianal fistulas
- in cases of mild postoperative changes in the anus and rectum, to create conditions for natural healing and regeneration
- to relieve postoperative pain and accelerate wound healing after open haemorrhoidectomy, i.e. haemorrhoid removal surgery
- after rectal radiochemotherapy, prostate radiotherapy, cervical cancer radiotherapy, when the main problem is late radiation proctitis – a clinical entity manifested by various objective and subjective symptoms, from diarrhoea to rectal fistulas (i.e. inflammation, mucosal defects); also in the treatment of rectal bleeding in the course of chronic radiation proctitis, with a predisposition to frequent bowel movements and late rectal pain (consultation with a doctor is recommended)
- prophylactically during chemotherapy, radiotherapy or a combination of both therapies to alleviate and reduce the symptoms of radiation proctitis and colitis
- in case of anal and rectal irritation in men undergoing transrectal prostate biopsy
- in case of anal irritation caused by environmental factors (underwear, hygiene products and others)
- in case of irritation of the anus and rectum after anal intercourse
- in cases of chronic prostatitis (prostate gland inflammation), benign prostatic hyperplasia and interstitial cystitis, but also bladder pain (e.g. in interstitial cystitis) and pain in the sacrum, coccyx and anus/rectum
- in the case of symptoms of prostatitis such as pain in the perineal area, mainly the anus. The product can be used in combination with other therapies to treat both bacterial and non-bacterial prostatitis. The use of the product in this situation is a therapy aimed at alleviating symptoms and ensuring a better quality of life. The product alleviates symptoms associated with both chronic prostatitis and the urinary tract. The direct effect on the rectum and the influence of the protective layer of hyaluronic acid on perineal tenderness may facilitate earlier therapeutic effects
- in the case of symptoms of inflammation and chronic pelvic pain in women, especially with symptoms of the lower urinary tract, where pain associated with urine accumulation and urination often overlaps, and in the case of chronic inflammation of anatomical structures anatomically and functionally related to the uterus: fallopian tubes, ovaries and supporting tissues.

After 20 days of treatment, if symptoms persist, consult your doctor about further use of the product.

The product can be used in long-term treatments, i.e. lasting longer than 30 days, in the following cases:

- to protect anal tissues in cases of persistent constipation in order to reduce friction during bowel movements, which protects against irritation and congestion in the anal area, providing relief
- for physiological lubrication of the anus in mature individuals, which improves the proper functioning of the anus (sphincter)
- as a preventive measure in people at risk of haemorrhoids (overweight people, people with a sedentary lifestyle, people who use laxatives, people who practise anal intercourse).

Preventative use: 1 to 2 times a day; duration - according to individual needs (can be used for more than 30 days).

Use for constipation to relieve pain: 1 to 2 times a day; duration - according to individual needs; (can be used for more than 30 days); use before bedtime is not required.

The product can be used every few days according to individual needs to moisturise and protect the rectal mucosa (can be used for more than 30 days).

The product contains safe substances that have been used for years and have a long history of use. If used as intended, the product does not pose a threat to health or life.

The product is intended for single-dose, single-use application. Do not attempt to return any unused portion of the product to the packaging, as this is contrary to the guidelines for use and storage of the product and may pose a risk of infection at the application site due to the stability of the product in connection with non-compliant storage conditions.

WARNINGS AND CONTRAINDICATIONS

Contraindications

- Do not use the product if you are hypersensitive (allergic) to any of its ingredients.
- Due to the lack of complete data, it is not recommended to use the product during pregnancy, unless it is absolutely necessary and under the direct supervision of a doctor supervising the pregnancy.
- If you experience heavy bleeding in advanced stages of haemorrhoids, occurring independently of bowel movements, you should contact your doctor. The use of the product in this situation is subject to the doctor's decision.
- Do not use the product in children. Medical device for rectal use in adults.

Warnings

- Do not use the medical device after the expiry date stated on the packaging.
- Do not use the product if the outer packaging has been damaged before first use.
- If symptoms persist or worsen after using the product, consult your doctor.
- Keep the product out of the reach of children.
- The product is intended for rectal use only. Do not swallow!
- The product is not intended for use in combination with other rectal products or rectal medicines. Do not use with other rectal products or rectal medicines!

STORAGE

- Store the product in its original packaging at a temperature of 15-25°C. Protect the product from light and heat sources.
- Keep the product out of the reach and sight of children.
- Do not use the product if the immediate packaging is damaged.
- Do not use the product after the expiry date stated on the packaging.
- 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.

Available product packaging:

Single-use product

Blister pack containing 5 suppositories in a single carton with instructions for use.

Blister pack containing 7 suppositories in a single carton with instructions for use.

Two blister packs of 5 suppositories (10 suppositories) in a

with instructions for use.





MANUFACTURER

LABORATOIRE L'IDEAL Parisien Sp. z o.o.
Ul. Ogrodowa 8, 32 – 064 Niegoszowice
Poland
tel./fax +48 12/ 283 88 60
www.lideal.pl



Medical device



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 15 September 2025

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 device
	Unique device identifier
	Do not use if the packaging is damaged.
	Read the instructions for use
	Keep away from direct sunlight