

Before using the device, read the instructions for use, as they contain important information for the patient on the use of the device. Keep the instructions for use so that you can read them again if necessary.

MEDCARE Suppositories for haemorrhoids

DESCRIPTION OF THE MEDICAL DEVICE

The medical device MEDCARE Suppositories for Haemorrhoids is intended for rectal use; it can be applied to the external anal area.

After application of the product, a protective layer is formed, which creates a favourable environment for the repair processes of the damaged mucosa.

The medical device MEDCARE Suppositories for Haemorrhoids creates a mechanical protective barrier on the mucous membrane of the anus or rectum, which supports the physiological healing process in the case of haemorrhoidal disease and its complications and after surgery to remove haemorrhoids. The product has a protective effect; this protective action relieves inflammation and itching and creates conditions suitable for the natural processes of damage regeneration and wound healing. The product provides the right conditions for healing lesions and reduces the risk of fissures and wounds caused by defecation. At the same time, it provides protection in the case of anal fissures and fissures that may develop as a result of constipation.

The protective layer contributes to post-operative pain relief after haemorrhoid removal surgery and creates conditions conducive to anal wound healing which speeds up the healing process.

The protective layer can be a prophylactic

- the extent of damage to the rectal mucosa as a result of radiotherapy, during chemotherapy, radiotherapy or a combination of both therapies, in order to alleviate and reduce the symptoms of radiation proctitis
- to protect the anal tissues in persistent constipation to reduce the sensation of friction during defecation, thus preventing irritation and congestion in the anal area, providing relief

The protective layer soothes irritation of the anal mucosa:

- for anal and rectal irritation in men undergoing transrectal prostate biopsy
- in case of irritation of the anus caused by environmental factors (underwear, hygiene products, etc.).
- for anal and rectal irritation after anal intercourse

MEDCARE Suppositories for haemorrhoids have a protective effect on the mucous membrane of the anus and rectum.

COMPOSITION

Composition: Sucralfate , Vitepsol H15

Product form: 2 g rectal suppository containing 500 mg sucralfate. One suppository is a single dose of the medical device.

Ingredients responsible for the essential action of the product

Sucralfate 25%

general information and indications

Indications for use of the medical device

- for the relief of symptoms associated with haemorrhoids accompanied by acute or chronic inflammation, pain, itching, bleeding; for internal and external haemorrhoids
- for itching, pinching, burning of the anus and discomfort caused by anal fissures and fissures (ragades) and eczema
- in anal fissures and fissures due to constipation
- for the relief of symptoms in ulcerative proctitis
- for benign rectal lesions to create the conditions for a natural healing and regeneration process
- to relieve post-operative pain and accelerate wound healing after open haemorrhoidectomy, i.e. surgery to remove haemorrhoids
- after prostate (prostate) radiotherapy, when the main problem is late post-radiation

Rectal inflammation - a clinical entity manifested by various physical and subjective symptoms,

from diarrhoea to rectal fistulas (i.e. inflammation, mucosal defects); also for the treatment of rectal bleeding in the course of chronic radiation proctitis (consultation with a doctor advisable)

- in patients with prostate cancer treated with radical radiotherapy with a probability of rectal tissue complications, with a predisposition for frequent bowel movements and late rectal pain (consultation with the doctor is advisable)
- after radiotherapy for cervical cancer, when the main problem is rectal bleeding and treatment of post-radiation proctitis (consultation with the doctor is advisable)
- prophylaxis of the extent of damage to the rectal mucosa caused by radiotherapy, prophylactically during chemotherapy, radiotherapy or a combination of both therapies to alleviate and reduce the symptoms of radiation proctitis
- to protect anal tissues in cases of persistent constipation
- for anal irritation in men undergoing transrectal prostate biopsy
- in case of irritation of the anus caused by environmental factors (underwear, hygiene products, etc.)
- in case of anal irritation after anal intercourse

MECHANISM OF ACTION OF THE PRODUCT

The application of the product is followed by the melting of the suppository and the formation of a protective layer by sucralfate.

The device works through a physical mechanism - it forms a protective layer on the surface of the anal and rectal mucosa, the protective layer allows the medical goal to be achieved.

The product persists on the rectal and rectal mucosa until the first defecation after application of the suppository. The product is removed from the site of application during defecation and during washing of the perirectal area.

METHOD OF APPLICATION

Wash your hands before applying the product!

Carefully remove 1 suppository from the pack.

Apply the suppository to the anus. It is not necessary to lie down during application.

Unless otherwise advised by your doctor, use 1 suppository before going to sleep.

Carry out the treatment for 14 days.

If use of the product is omitted, do not use a double dose, i.e. 2 caps. In case of persistent symptoms consult further use of the product with a doctor. Prophylactic use -1 suppository per day; in time - according to individual need.

Use for constipation relief - 1 suppository at a time - according to individual need; use before bedtime is not required.

The product can be used every few days according to individual needs to protect the anal mucosa. The product is intended for rectal use only.

Medical device for rectal use for adults.

Pregnant and lactating women may use the product after consultation with a doctor and under the direct supervision of the doctor supervising the pregnancy.

The product can be used in therapies lasting up to 30 days. The product contains safe substances that have been used for years, with a long history of use. If used as intended, the product poses no risk to health and life.

The product is intended to be used in single doses for a single use. Do not attempt to reinsert any unused portion of the product into the packaging as this is not in accordance with the guidelines for use and storage of the product and may carry the risk of infection at the application site as a result of loss of stability of the product due to incompatible 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, the use of the device during pregnancy is not recommended unless absolutely necessary and under the direct supervision of the doctor supervising the pregnancy.
- Increased bleeding in advanced haemorrhoids occurring independently of bowel movements is a situation where a doctor should be contacted. The use of the product in this situation is at the doctor's discretion.
- Do not use the product with other rectal products and medicines
- Do not use in children. Medical device for rectal use for 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 is damaged before first use.
- If symptoms persist or do not alleviate after using the product, a doctor should be consulted.
- Use the device immediately after taking a dose from the package, i.e. from the blister. A product removed from the blister cannot be used at a later date.
- A single suppository in a blister is a dosage for a single use, the unused amount must be disposed of in accordance with current regulations.
- Keep the product out of the reach of children.
- The product is intended for rectal use only. Do not swallow!

STORAGE

- Store the product in its original packaging at 15-25oC.
- Protect the product from light and sources of heat.
- 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 on the packaging.
- An empty container, unused or out-of-date product should be disposed of (recycled) in accordance with applicable rules. The medical device does not contain substances harmful to the environment.

Product packaging available:

Single-use product

Blister containing 2 suppositories in a single carton with instructions for use
 Blister containing 5 suppositories in a single carton with instructions for use.
 Blister containing 7 suppositories in a single carton together with instructions for use.
 Two blister packs of 5 suppositories (10 suppositories) in a unit carton with instructions for use.
 Four blister packs of 5 suppositories (20 suppositories) in a unit carton with instructions for use.



PRODUCER

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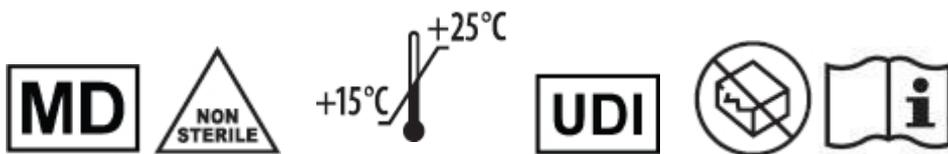
DISTRIBUTOR



Medical device



Information on the blister and on the carton



Adverse reactions and serious incidents relating to the use of a medical device should be reported to the manufacturer or distributor and to the relevant national authority.

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