

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 Rectal Gel

DESCRIPTION OF THE MEDICAL DEVICE

MEDCARE medical device rectal gel is intended for rectal application; it can be applied to the external rectal area. After application of the product, a protective layer is formed, which creates a favourable environment for the repair processes of the damaged mucosa.

MEDCARE medical device Rectal Gel 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

The product has a protective effect on the anal and rectal mucosa.

COMPOSITION

Composition: Purified water, Hydroxyethylcellulose, Phenoxyethanol, Ethylhexylglycerol, Sucralfate, Aluminum sucrose acetate sulfate, Sorbitol, Sodium dihydrogen phosphate dihydrate, Disodium hydrogen phosphate, dodecahydrate, Sodium hydroxide.

Product form: single-use applicators of 5 ml rectal gel; each applicator contains 500 mg sucralfate

One applicator is a single dose of a medical device.

Ingredients responsible for the essential action of Sucralfate 10%

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
- in the case of benign rectal lesions, to create the conditions for a natural process

healing and
regeneration

- to relieve postoperative pain and accelerate wound healing after open haemorrhoidectomy, i.e. surgery to remove haemorrhoids
- after radiotherapy to the prostate (prostate), when the main problem is late radiation proctitis - a clinical entity manifested by various physical and psychological symptoms, from diarrhoea to rectal fistulae (i.e. inflammation, loss of mucous membrane); also for the treatment of rectal bleeding in the course of chronic radiation proctitis (consultation with the doctor is 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.)
- for anal and rectal irritation after anal intercourse

MECHANISM OF ACTION OF THE PRODUCT

The application of the product is followed by the formation of a protective layer.

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 device remains on the anal and rectal mucosa until the first defecation after application of the device. The device is removed from the application site during defecation and during washing of the perirectal area.

METHOD OF APPLICATION

Wash your hands before applying the product!

Apply the product to the anal canal (internally) or externally to the anal area.

Internal application: the gel should be applied into the anal canal, using a disposable applicator, which represents the amount of the medical device for a single use; squeeze the entire contents of the applicator into the anal canal.

The product diffuses into the anal canal immediately after application, and no lying position is required during application.

External application: Apply the contents of a disposable applicator to the anal area. It is recommended to apply the gel in the evening before bedtime.

Carry out the treatment for 14 days.

If the product is missed, do not use a double dose, i.e. two applicators per application.

If symptoms persist, consult further use with your doctor. Prophylactic use 1 to 2 times a day over time - according to individual need.

Use for constipation relief 1 to 2 times a day over 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 and rectal mucosa; in this case, use 1-2 times a day.

The product is intended only for rectal use or on the external anal area. Do not take the product orally.

Unless otherwise advised by the doctor, use 1 applicator, i.e. 5 ml of the product before going to sleep. 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.
- 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 15-25^(o) C.
- 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 discarded (recycled) in accordance with applicable rules. The medical device does not contain substances harmful to the environment.

Product packaging available:

Single-use product

1 applicator 5ml in a single cardboard box with instructions for use

2 applicators 5ml in a single cardboard box with instructions for use

5 5ml applicators in a single carton including instructions for use .

7 5 ml applicators in a unit carton with instructions for use.

10 5 ml applicators in a unit carton with instructions for use.

14 5 ml applicators in a single carton including with instructions for use.

20 5 ml applicators in a unit carton with instructions for use.





PRODUCER

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Medical device

DISTRIBUTOR



Information on the blister and on the carton

LOT



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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