

Instructions for use
fytofontana HEMORRELAX rectal suppositories



Before use, read the instructions for use carefully.
Keep the instructions for use for possible future reference.

Hemorrhoidal disease is one of the most widespread illnesses, and according to statistics, it affects up to 75% of people over the age of 25 during their lifetime. Hemorrhoidal disease (piles) causes psychological stress, often accompanied by pain, discomfort, and an overall impact on quality of life, especially in more advanced stages.

Hemorrhoids (veins in the rectum) are a natural part of every human body. They act as an elastic, watertight seal and play an irreplaceable role in maintaining and controlling bowel movements. Problems arise when hemorrhoidal disease develops, during which hemorrhoids enlarge, become inflamed, and may form blood clots. From an anatomical point of view, the rectal mucosa is lined with a dense vascular network that provides nutrition to the surrounding tissue. Under excessive pressure, the blood vessels become dilated, blood accumulates in them, and nodes may form (similar to varicose veins).

In the treatment of hemorrhoids, the first step is lifestyle adjustment- adequate physical activity, strengthening of the pelvic floor, dietary regulation, regular and proper bowel movements, and hygiene. Conservative treatment (creams, suppositories, sitz baths) aims to alleviate mild symptoms such as irritation, sensitivity, itching, and pain in the rectal area associated with hemorrhoids and other rectal conditions.

Ingredients: oak bark extract (0.04 g), horse chestnut seed extract (0.04 g), calendula flower extract (0.04 g), chamomile flower extract (0.04 g), sodium hyaluronate (0.002 g), laureth-9, dimethicone, acetyl hexapeptide-1, pentapeptide-18, PEG-32, polysorbate 20, PEG-20

Purpose of use

The medical devices fytofontana HEMORRELAX rectal suppositories help to relieve unpleasant accompanying symptoms occurring in internal hemorrhoids in connection with hemorrhoidal diseases and other diseases of the rectum such as anal fissures and ragades. They are intended for insertion into the rectum locally onto the rectal mucosa in internal hemorrhoids.

Indications

- Irritation of the rectal mucosa (irritation after diarrhoea, hemorrhoids, or after medical procedures),
- hemorrhoids (supportive treatment in internal hemorrhoids),
- anal cracks (anal fissures and ragades),
- dryness or atrophy of the rectal mucosa (moisturizing, restoration of elasticity).

Main mechanism of action

The medical devices fytofontana HEMORRELAX rectal suppositories act through local interaction in the rectum, while they dissolve and their active substances are released and act at the site of application and also help the healing of small wounds in the rectal area (anal fissures and ragades). Emphasis is placed on the use of herbal natural preparations containing flavonoids, which have regenerative properties, strengthen the vessel wall and at the same time alleviate the unpleasant feelings accompanying the acute phase of hemorrhoidal disease. These preparations locally support healing, moisten, soothe, and hydrate the rectal mucosa. Thanks to peptides which act like botulinum toxin, they help to calm the spasmodic contraction of the anal sphincter muscle, which also helps painless emptying. Hyaluronic acid moisturizes and regenerates damaged epithelial cells in tissues, maintaining healthy rectal mucosa. The combination of herbal ingredients, peptides,

hyaluronic acid and lubricating component has antimicrobial, antiseptic, astringent, anti-inflammatory and anaesthetic effects.

Rectal suppositories thanks to these properties help to relieve unpleasant accompanying symptoms occurring in internal hemorrhoids. They bring immediate relief from unpleasant symptoms such as burning, itching, pain in the rectal area. They do not focus only on suppressing acute symptoms, but soothe and act preventively. It is not a metabolic, pharmacological or immunological effect in internal hemorrhoidal disease.

The main benefit for the user/patient is local therapy in the form of rectal suppositories for relief from pain and alleviation of symptoms of hemorrhoidal diseases, mainly including pain, itching, burning or swelling in the rectal area. All components of the medical device are aimed at alleviating irritation, inflammation and supporting healing in the rectal area in hemorrhoids and in other diseases of the rectum such as anal fissures and ragades. Rectal suppositories act through local interaction in the rectum, where they dissolve and their active substances are released and act at the site of application on the rectal mucosa, thereby also improving the overall quality of life for the adult population.

Intended users / patients

The medical device is intended for use by adults from 18 years of age who suffer from unpleasant accompanying symptoms occurring in internal hemorrhoidal diseases.

Dosage and method of use

Application of 1 suppository once daily is recommended, preferably in the evening, after evening hygiene, by application into the rectum.

Before and after using fytofontana HEMORRELAX rectal suppositories we recommend maintaining hygiene, thoroughly wash your hands as well as the treated area.

The suppository must be removed by pulling on the two cut wings of the blister and 1 suppository per day is used by application into the rectum.

Contraindications

- allergic reaction and hypersensitivity as a reaction of the human body to any component,
- acute inflammation, infection, or abscess in the rectal area,
- neoplastic diseases of the rectum,
- rectal or anal injuries in the acute phase.

Warning, caution:

⚠ Use of the device is not recommended for people suffering from chronic constipation (they need to force or possibly manually stimulate the passage of stool), as well as for people who have problems with retaining stool.

⚠ Do not use during pregnancy.

⚠ If irritation or worsening occurs, immediately stop using the product and contact your doctor.

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

⚠ Do not use after the expiry date indicated on the package.

⚠ Do not swallow. For rectal use only.

⚠ Keep out of reach of small children.

Precautionary measures:

△ Rectal suppositories are recommended to be applied after defecation. After use it is recommended to wash your hands thoroughly.

△ Do not use other products on the treated area at the same time.

△ Possible colour change is caused by natural herbal substances contained in the product and is not a defect of the product.

Package contents: 10 rectal suppositories

Storage

The data are indicated on the packaging

Lifetime of the medical device

The lifetime period of the medical device is determined by the expiry date on the product package- 36 months from the date of manufacture.

Accessories or compatible MD

The MD fytofontana HEMORRELAX rectal suppositories has no accessories and no compatible medical devices.

Disposal: Return any unused product to the pharmacy. Dispose of clean packaging material in the appropriate container for sorted waste.














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**Further information**

In the event of a serious incident caused by the device, the user should report this incident to the manufacturer and to the competent authority of the Member State in which the user is resident.

EXPLANATION OF SYMBOLS

	See instructions for use		Manufacturer
	Use by		Batch number
	Temperature limit		Protect from sunlight
	Conformity marking		Medical device
	Reference number		Unique identifier of the device
	Warning		

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