

FAKTU® Ointment

for rectal (internal and external) application

Composition

1 g of ointment contains:

Active ingredients

Policresulen 50 mg
Cinchocaine hydrochloride 10 mg

Excipients

Sodium hydroxide; Cetomacrogol, in form of Cremophor A6; butylhydroxytoluene; disodium edetate; silica, colloidal anhydrous; mixture of equal weights of macrogol 300 and macrogol 1500 (Polywachs 500); macrogol 400; purified water; water from the policresulen raw material solution

Pharmaceutical form and contents

Ointment
Packs with 20 g of ointment

Pharmacotherapeutic / indication group / action mechanism

Antihemorrhoidal agent

Holder of the marketing authorization / Manufacturer

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Indications:

Haemorrhoids, particularly when accompanied by inflammatory symptoms and bleeding, anal fissures, anal rhagades, anal pruritus, anal eczema, caused by anorectal conditions, wound treatment after proctological operations.

Contraindications:

During pregnancy policresulen must be used only when strictly indicated, with due assessment of the risks to the mother and child. Studies in animals have not yielded any evidence of malformations. No studies are available on the risk of use during pregnancy in humans. It is not known whether the active ingredient passes into milk.

Patients with hypersensitivity to cinchocaine must not use Faktu ointment unless expressly instructed to do so by the doctor.

Special warnings and precautions for use

Pregnancy and lactation

During pregnancy policresulen must be used only when strictly indicated, with due assessment of the risks to the mother and child. Studies in animals have not yielded any evidence of malformations. No studies are available on the risk of use during pregnancy in humans. It is not known whether the active ingredient passes into milk.

Effects on the ability to drive and to use machines
According to the information available so far, when Faktu ointment is used as prescribed does not affect the ability to drive or to operate machinery.

Interactions

Unknown

THIS IS A MEDICAMENT

A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacists are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor
- Keep all medicaments out of the reach of children.

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Posology and method of administration

Unless otherwise recommended, apply the ointment 2-3 times a day to the affected area, rubbing it in if possible. Apply to the rectum after a bowel movement, using the applicator provided.

Instructions for use / handling

Thread the applicator onto the tube, insert it into the rectum, and press gently. Faktu ointment flows uniformly through the holes in the side of the applicator onto the affected area. Turning the tube slightly helps to spread the ointment. Many haemorrhoids occur directly in the anal canal, and the Faktu applicator was developed especially for this condition. The holes in the special nozzle allow Faktu ointment to flow directly to the area of pain and discomfort.

Incorrect use and overdosage

Not applicable

Undesirable effects

The occasional discomfort (e.g. burning or itching) is caused by the active ingredient and in most cases disappears after a short time. There have been isolated cases of allergic contact sensitivity, manifested as inflammatory reddening of the skin (erythema) with the formation of vesicles (papules) accompanied by persistent itching (pruritus). If this happens the treatment must be stopped and a doctor consulted.

If you experience any side effects not listed in this package leaflet, please inform your doctor or pharmacist.

Storage conditions and shelf life

Faktu ointment stored below 25 °C remains unchanged for 5 years.

The expiry date of this pack is printed on the container and on the folding box.

Do not use this pack after the expiry date!

Date of last revision of the text

July 2002