

FAKTU[®] suppositories

for rectal (internal) application

Composition:

1 suppository contains:

Active ingredients

Policresulen 100 mg

Cinchocaine hydrochloride 2.5 mg

Excipients

Sodium hydroxide; silica, colloidal anhydrous; cellulose, microcrist.; soybean lecithin, liquid; hard fat

Pharmaceutical form and contents

Suppositories

Packs with 10 suppositories

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 anaerobic 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 suppositories 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 suppositories are used as prescribed do 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 prescribed, the following dosage scheme applies. Please follow these instructions, otherwise there is a risk that the drug may not act properly!

Unless otherwise recommended, insert one suppository into the rectum 2-3 times a day, after emptying the bowel, in the morning and in the evening and, if required, any time during the day. As the symptoms improve treatment can be continued with one suppository per day.

Instructions for use / handling

Insert suppositories deeply into the rectum.

Incorrect use and overdoseage

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

Countermeasures

If you experience undesirable effects, stop treatment and consult your doctor.

Storage conditions and shelf life

Faktu suppositories stored below 25 °C remain unchanged for 3 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!

Any variation in the suppositories' colour or the presence of light-coloured flecks (fatty deposits) are harmless and have no effect on efficacy.

Date of last revision of the text

July 2002