

PACKAGE LEAFLET: INFORMATION FOR THE USER

FAKTU

100 mg + 2.5 mg suppository

POLICRESULEN, CINCHOCAINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What FAKTU tablets is and what it is used for
2. Before you take FAKTU
3. How to take use FAKTU
4. Possible side effects
5. How to store FAKTU
6. Further information

1. WHAT FAKTU IS AND WHAT IT IS USED FOR

FAKTU is used for the treatment of Hemorrhoids, particularly when accompanied by inflammatory symptoms and bleeding, anal fissures, anal rhagades (minor injury of the lining of the colon) anal pruritus, anal eczema, caused by anorectal conditions, wound treatment after proctological operations.

2. BEFORE YOU TAKE FAKTU

Do not take FAKTU

- If you are allergic to Policresulen, cinchocaine, or any of the other ingredients of this medicine FAKTU suppositories contain phospholipids derived from soybeans. If you are allergic to soy or peanuts, do not use FAKTU suppositories.

Taking other medicines

Interactions unknown.

Pregnancy and breastfeeding

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.

3. HOW TO TAKE FAKTU

Always take FAKTU exactly as you are told by your doctor. If you are unsure, check with your doctor or pharmacist.

Unless otherwise prescribed, the following dosage scheme applies. Please follow these instructions, otherwise there is a risk that the drug may not act properly!

How many you should use and how often?

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.

When and how to use the suppository?

FAKTU suppository is applied after a bowel movement. FAKTU suppositories should be inserted into rectum morning and evening, and if necessary during the day, after a bowel movement.

How long should I use FAKTU suppository?

The length of treatment is determined by the doctor.

If you take more FAKTU than you should

If you have used too much FAKTU suppository, tell your doctor.

If you forget to take FAKTU

If you miss a dose, apply the next dose at the usual time and continue to use the medicine as instructed by a doctor.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, FAKTU can cause side effects, although not everybody gets them.

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Countermeasures

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

5. HOW TO STORE FAKTU

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use FAKTU after the expiry date which is stated on the on the tube and the folding box, 3 years from the date of manufacture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What FAKTU contains

The active substances are polikrezulen and cinchocaine hydrochloride. 1 gram of suppository contains 100 mg of policresulen and 2,5 mg of cinchocaine hydrochloride.

Other ingredients: Sodium hydroxide; silica, colloidal anhydrous; cellulose, microcryst; soybean lecithin, liquid; hard fat

What FAKTU looks like and contents of the pack

FAKTU suppositories are creamy to reddish brown.

Packaging:

2 strips with 10 suppositories

1 strip containing 5 suppositories

Regime of dispensing

The medicine is issued without a doctor's prescription.

Manufacturer

NYCOMED GMBH

BYK-GULDEN-STRABE 2, KONSTANZ, GERMANY

Manufacturer of the medicinal product

NYCOMED GMBH

PRODUCTION SITE IN SINGEN

ROBERT BOSCH STRASSE 8, SINGEN, GERMANY