

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### FAKTU

(50 mg + 10 mg) / g ointment

POLICRESULEN, CINCHOCAINE

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*• 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.*

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*• 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 •*

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#### 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

##### **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?***

You should apply the ointment to the affected area 2 to 3 times a day.

#### ***When and how to use the ointment?***

If possible, ointment should be rubbed. For rectal use, ointment is applied after a bowel movement. For use in the rectum use the enclosed applicator / cannula. Attach the applicator / cannula to the tube and insert it into the anus. Gently squeeze the tube so that the ointment evenly passes through the holes along the applicator / cannula to the affected area. Gently rotate the tube to facilitate the distribution of fat.

#### ***How long should I use FAKTU ointment?***

The length of treatment is determined by the doctor.

#### ***If you take more FAKTU than you should***

If you have used too much FAKTU ointment, 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, 5 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 ointment contains 50 mg of polikrezulena and 10 mg of cinchocaine hydrochloride.

Other ingredients: cetomacrogol, butylated hydroxytoluene, edetic acid, disodium edetate (Ph. Eur.), Colloidal silica, macrogol 300, macrogol 400, macrogol 1500, sodium hydroxide, water.

### **What FAKTU looks like and contents of the pack**

FAKTU ointment is white to light brown.

Packaging

20 grams of ointment in a tube. Tube with applicator in cardboard packaging.

### **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