

**痔克妥栓劑**  
Faktu® Suppositories  
(衛署藥輸字第 016450 號)

**【組成】**

栓劑：每個栓劑 Policresulen 100mg 和 Cinchocaine hydrochloride 2.5mg  
賦形劑：sodium hydroxide, silicon dioxide, colloidal anhydrous,  
cellulose, microcryst. phospholipids from soy bean, edetic acid, hard fat.

**【適應症】**

痔瘡及肛門直腸裂隙和破裂所引起之疼痛、出血、搔癢及發炎。

**【禁忌】**

- \*對 Cinchocaine 過敏者不可使用。
- \*懷孕期必須估算出對母體及胎兒的全部可能危險。在絕對需要時才可使用。
- \*動物試驗沒有發現任何畸胎形成使用於懷孕婦女所可能的危險研究報告尚未提出，仍不知道主成分是否會存在哺乳母親的乳汁中。

**【副作用】**

在開始治療時偶有極輕微的局部不適，如：癢、燒灼感。但通常能迅速消退，不須停藥。

**【用法、用量】**

栓劑：本要須由醫師處方使用。

每天 2-3 次，每次一個，於排便後塞入。症狀消除後，可改為每天一個栓劑。

**【注意】**

貯存於 25°C 以下。

注意包裝上的有效期限。

栓劑可能會變色以及包裝可能會破損，但不會影響產品的有效性。

貯存時必須需小心，勿讓兒童觸及。

**【包裝】**

栓劑：100 粒以下盒裝

製造商：Takeda GmbH  
Robert-Bosch-Str. 8,  
D-78224 Singen, Germany

藥商：瑞慶藥業有限公司  
台北市南京西路30號8樓之3  
TEL：(02) 2550-1226

Insert leaflet

# Faktu<sup>®</sup> 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

Takeda GmbH

Byk-Gulden-Strasse 2

D-78467 Konstanz

Germany

Telephone: ++49(0)7531-84-0

Telefax: ++49(0)7531-84-2474

### 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 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 overdose

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

