

LFT. FAKTU OINT & SUPPO (TAKEDA)
Ukuran : 120 x 190 mm (1/1)

Keterangan:

Black

FAKTU[®]
Ointment and Suppository

COMPOSITION

- **FAKTU[®] Ointment**
1 g contains 50 mg of policresulen and 10 mg of cinchocaine hydrochloride.
- **FAKTU[®] Suppository**
1 suppository contains 100 mg of policresulen and 2.5 mg of cinchocaine hydrochloride.

ACTION AND USES

FAKTU[®] for use in the treatment of haemorrhoidal conditions is available as ointment and suppository.

Both presentation forms contain policresulen and the local anesthetic cinchocaine as active substances. The astringent, bactericidal and haemostatic actions of FAKTU[®] have proved useful in the therapy of anorectal diseases. The essential active principle of FAKTU[®]: policresulen exerts a selective action upon necrotic tissue without affecting healthy epithelium. Pathologically changed tissue is coagulated to be subsequently cast off. Bleedings are promptly controlled, since a protective film is formed upon wound areas, consisting of denatured protein and anal capillaries are constricted and closed.

Oozing and itching are removed. Regeneration is further promoted by the hyperemic effect induced by the preparations. The bactericidal effect of FAKTU[®] prevents or controls inflammatory processes. Cinchocaine has shown to be useful in proctology, providing relief of pain and itching. FAKTU[®] quickly eliminates bleeding, oozing, and itching in haemorrhoidal diseases and other anorectal disorders, prevents inflammation and stimulates the regeneration of the affected tissue.

INDICATIONS

- Haemorrhoids
(FAKTU[®] ointment for internal and external use. FAKTU[®] suppository for the treatment of internal haemorrhoids), especially those associated with inflammatory conditions or bleeding.
- Anal fissures

DOSAGE AND ADMINISTRATION

Ointment:

The ointment is applied 2 - 3 times daily to the affected area. Rectal insertion of ointment requires prior evacuation of bowel; use enclosed applicator for introduction.

Suppository:

1 suppository 2 - 3 times daily following prior evacuation. After cessation of symptoms treatment may be maintained with one suppository daily.

CONTRAINDICATION

FAKTU[®] must not be used in case of hypersensitivity to cinchocaine or to any of the excipients. FAKTU[®] suppositories contain phospholipids from soya beans. In case of hypersensitivity to soya or peanuts, FAKTU[®] suppositories must not be used.

UNDESIRABLE EFFECTS

The following frequency convention is used in the evaluation of side effects:

Very common: more than 1 in 10 patients treated.
Uncommon: less than 1 in 100, but more than 1 in 1,000 patients treated.
Common: less than 1 in 10, but more than 1 in 100 patients treated.
Rare: less than 1 in 1,000 more than 1 in 10,000 patients treated.
Very rare: less than 1 in 10,000 patients treated, including isolated cases.

Skin and subcutaneous tissue

Uncommon: discomfort (e.g. burning or pruritus). This is caused by the active substance and in most case resolves after a short time.

Very rare: There may be isolated cases of allergic contact sensitivity. This may manifest as

inflammatory reddening of the skin (erythema) with formation of vehicle (papules) accompanied by persistent itching (pruritus).

Immune system disorders

Very rare: There have been isolated reports of systemic allergic reactions (e.g. angioedema, laryngeal oedema, generalized urticaria) and even anaphylaxis. In such cases, treatment is to be discontinued and a doctor consulted.

WARNINGS AND PRECAUTIONS

Apply only to the region of the rectum and anus and surrounding skin.

Mild local discomfort such as burning or itching, associated with the therapeutic mechanism of the preparations, may sometimes be noted at the beginning of treatment, usually subsiding rapidly. Discontinuation of medication, therefore, is generally not required. In persons sensitive to any of the ingredients, skin rash may occur.

STORAGE

FAKTU[®] Ointment: Store below 30°C.

FAKTU[®] Suppository: Store at (2-8)°C: *temperature not exceeding 25°C* *21/5/19*

PRESENTATION

FAKTU[®] Ointment

Box, tube of 20 g
Reg. No. DKL8121600930A1

FAKTU[®] Suppository

Box of 2 strip @ 5 suppositories
Reg. No. DKL7621609553A1

On Medical Prescription Only
HARUS DENGAN RESEP DOKTER

Store drug carefully and out of the reach of children

Manufactured by:

PHAROS
Jakarta - Indonesia

Under license from:

Takeda

TAKEDA-GmbH
D-78467 Konstanz
Germany

