PRODUCT INFORMATION

Procto-Synalar®

Ointment, suppositories

GRÜNENTHAL

Dermatogical preparations (combination of a topical corticoid and a local anaesthetic)

Composition

Ointment: fluocinolone acetonide 0.1 mg, lignocaine hydrochloride 20.0 mg, propylene glycol 70.0 mg, preservatives: propyl-4-hydroxybenzoate (E 216) 0.5 mg, methyl-4-hydroxybenzoate (E 218) 1.5 mg, excipients ad 1 g ointment.

Suppositories: fluocinolone acetonide 0.1 mg, lignocaine hydrochloride 40.0 mg, excipients per suppository.

Characteristics/Effects

Fluocinolone acetonide, the topical corticoid in Procto-Synalar, has a pronounced anti-inflammatory, anti-allergic, antipruritic and anti-exudative effect. Topical corticoids are usually divided into four groups - very potent, potent, moderate, and weak - and Procto-Synalar is classified as a moderate topical corticoid preparation. Additional pain relief is achieved with the local anaesthetic lignocaine.

Pharmacokinetics

Pharmacokinetic investigations with the active substance combination present in Procto-Synalar have so far not been carried out. It is, however, known that the degree of cutaneous corticoid absorption mainly depends on the mode of application, such as open treatment or under an occlusive dressing, the area treated, the moisture content and in particular the condition of the skin. In healthy volunteers treated for three weeks with 15 g fluocinolone acetonide cream (0.025%) daily, applied to about 1200 cm^2 of dorsal skin, a mean reduction in the urinary excretion of 17-ketosteroids of up to 1.3% was found. Consequently, the systemic effect of topical fluocinolone acetonide is negligible when used according to instructions. Long-term use or treatment with doses higher than those recommended may, however, cause systemic corticoid effects.

Assuming that the fluocinolone acetonide from two Procto-Synalar suppositories per day or 1 g Procto-Synalar ointment twice daily is completely absorbed, this corresponds to a dose of 0.2 mg fluocinolone acetonide/day. According to CAHN and LEVY no systemic side-effects were observed in humans after oral administration of 4 mg fluocinolone acetonide daily for 90 days.

If it is also assumed that the dose of lignocaine is completely absorbed, peak plasma concentrations would be less than 0.1 µg/ml per gram ointment or less than 0.2 µg/ml per suppository. Concentrations of less than 1 µg/ml however, have no systemic effect. In order to achieve an anti-arrhythmic effect, lignocaine plasma levels must reach 1-5 µg/ml (KRAUPP). Consequently the risk of systemic side-effects is low.

Indications

Internal and external haemorrhoids, anal eczema, proctitis, pruritus ani, pre- and postoperative treatment.

Dosage/Application

Before application of Procto-Synalar and after each defaecation, the anal region must always be thoroughly cleansed with warm water and a soft or disposable cloth - if possible without soap.

Procto-Synalar *ointment* is to be applied twice or three times daily and gently smoothed in. The ointment can also be applied intrarectally with the aid of the applicator enclosed in the pack.

Procto-Synalar *suppositories* are to be inserted mornings and evenings after defaecation.

Duration of Administration

The duration of treatment depends on the clinical picture and usually does not exceed 2–3 weeks. If longer treatment is necessary, the patient's condition should be checked and a decision made as to whether treatment should be continued or repeated.

Restrictions

Contraindications

Procto-Synalar is contraindicated in tuberculous, syphilitic, primarily fungal, bacterial or viral diseases in the region to be treated.

On known intolerance to any component of the ointment or suppositories, or on the occurrence of intolerance during treatment, the respective preparation must not be used or must be discontinued.

Infants and young children are not to be treated with Procto-Synalar, as sufficient experience on treatment in these age groups is not yet available.

Precautions

As with all topical corticoids, long-term treatment may cause dermal or mucosal atrophy.

Pregnancy/Lactation

Pregnancy category C

Animal experiments have shown that the topical administration of potent corticosteroids is teratogenic, but no controlled human studies are available. During pregnancy topical corticosteroids should only be used when the potential benefit is greater than the foetal risk. They should not be applied to extensive areas, in high doses, or over long periods during pregnancy.

Glucocorticoids pass into the milk. Therefore breast-feeding should not take place during long-term therapy or treatment of large areas of the body.

Side-effects

In isolated cases there may be initial brief smarting. In rare cases local irritation, pruritus, hypersensitivity reactions and secondary infections may occur after application of Procto-Synalar. After long-term treatment with Procto-Synalar the possibility of dermal atrophy in the treated area cannot be ruled out.

Other Points

Procto-Synalar suppositories must not be stored above 30°C, even for short periods.

Procto-Synalar must not be used after the expiry date printed on the packing.

Presentations

Procto-Synalar ointment:	Tubes of 15 g
Procto-Synalar suppositories:	Pack containing 10 suppositories

Distributors and Manufacturers

Grünenthal Pharma AG, 8756 Mitlödi

Date of Information

February 1995

THIS IS A MEDICAMENT

– 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 pharmacist are 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 REACH OF CHILDREN

Council of Arab Health Ministers
Union of Arab Pharmacists

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