PRODUCT INFORMATION

Synalar® Cream, Ointment, Lotion, Gel

GRÜNENTHAL

Topical corticosteroid

Composition *Synalar cream:* Active ingredient: fluocinolone acetonide 0.25 mg. Excipients: propylene glycol, preservatives: propyl-4-hydroxybenzoate (E 216), methyl-4-hydroxybenzoate (E 218), further excipients ad 1 g.

Synalar ointment: Active ingredient: fluocinolone acetonide 0.25 mg. Excipients: propylene glycol, wool fat, further excipients ad 1 g.

Synalar lotion: Active ingredient: fluocinolone acetonide 0.25 mg. Excipients: propylene glycol, preservatives: propyl-4-hydroxybenzoate (E 216), methyl-4-hydroxybenzoate (E 218), ß-phenylethyl alcohol, further excipients ad 1 ml.

Synalar gel: Active ingredient: fluocinolone acetonide 0.25 mg. Excipients: propylene glycol, preservatives: propyl-4-hydroxybenzoate (E 216), methyl-4-hydroxybenzoate (E 218), further excipients ad 1 g.

Characteristics/Effects Fluocinolone acetonide, the topical corticosteroid in Synalar, has a pronounced anti-inflammatory, anti-allergic and antipruritic effect. Topical corticosteroids are divided into four groups - very potent, potent, moderate and weak - and the fluorinated corticosteroid contained in Synalar is a potent topical corticosteroid preparation.

Pharmacokinetics The degree of cutaneous corticosteroid absorption mainly depends on the mode of application, such as open treatment or under an occlusive dressing, the age of the patient, the part of the body, the area treated, the moisture content and condition of the skin, and the pharmaceutical formulation. In the case of hydrocortisone, about 1% of the amount applied penetrates normal skin, about 3% after removal of the horny layer, and about 10% under an occlusive dressing.

In healthy volunteers who were treated for three weeks with 15 g fluocinolone acetonide cream (0.025%) daily, applied to about 1200 cm^2 of dorsal skin, there was a mean reduction in the urinary excretion of 17-ketosteroids of up to 1.3%. Consequently, the systemic effect of locally applied fluocinolone acetonide is negligible when used according to instructions. This has been confirmed by a large number of clinical studies.

No penetration studies have been performed with the other formulations (gel, ointment, lotion).

Indications Non-infective inflammatory, pruritic and allergic skin diseases.

Synalar *cream* is particularly indicated in acute and subacute stages, in weeping processes, and for greasy skin.

The non-aqueous Synalar *ointment* is suitable for chronic and dry processes.

Synalar *lotion* is indicated in acute, weeping, and seborrhoeic dermatoses; Synalar lotion is particularly suitable for intertriginous and hairy parts of the body.

Synalar *gel* is suited for exposed parts of the body.

Dosage/Application Apply sparingly to the affected parts of the skin once or twice daily.

The duration of treatment depends on the therapeutic success and usually amounts to not more than 2–3 weeks.

If long-term treatment is necessary, the patient's skin should be checked medically and attention paid for any signs of changes in plasma cortisol. A decision should then be made as to whether treatment is to be continued or repeated.

Restrictions *Contraindications* Synalar is contraindicated in tuberculous or syphilitic skin diseases, vaccination reactions, fungal, bacterial or viral skin infections and acne. Ophthalmic application, perioral dermatitis and rosacea are contraindicated.

On known intolerance to any component of the cream, ointment, lotion or gel the respective preparation must not be used.

Precautions In order to ensure the greatest possible therapeutic safety, long-term treatment and application to large areas, particularly under occlusion, should be avoided, if possible, in patients in whom systemic corticosteroid therapy is contraindicated. If it is carried out, the precautions applying to systemic corticosteroid therapy should be taken.

The application of potent corticosteroids in high doses, to extensive areas or under occlusion should only be carried out under regular medical supervision, particularly with regard to the suppression of endogenic corticosteroid production.

If possible, the preparation should not be applied continuously for more than 2–3 weeks.

In case of dermal infections and ulcers topical corticosteroids should only be used with care and additional treatment of the infection. The possibility of impaired wound healing must be taken into account.

If a dermatosis does not respond adequately to treatment or even deteriorates, the diagnosis should be reviewed, particularly in the light of an allergy to one of the active substances or an infection (fungi etc.).

Corticosteroids may mask symptoms of an allergic dermal reaction to a component of the preparation.

The patient should be advised that the preparation is to be used only for his particular disease and it is not to be passed on to other people.

In children, particularly infants and toddlers, percutaneous absorption is raised and therefore systemic side-effects, such as growth disturbances, may occur on long-term treatment.

As with all potent fluorinated corticosteroids, care is necessary when applying Synalar to the face or genital region, and treatment should not be carried out for more than one week.

Pregnancy/lactation Pregnancy catergory C

Animal experiments have shown that the topical administration of potent corticosteroids is teratogenic, but no controlled human studies have been made. During pregnancy corticosteroids should only be used topically 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.

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

Side-effects Local side-effects such as dermal irritation, smarting, pruritus, dryness and hypersensitivity reactions to a component of the preparation may occur, particularly at the beginning of treatment.

On the topical administration of Synalar to large areas (more than 1/5 of the body surface) and/or over long periods the following local side-effects have been reported: dermal atrophy, namely on application to the face, genital region or skin folds, striae distensae, telangiectasia, purpura, decrease in skin pigment, steroid acne, manifestations of irritation, perioral dermatitis, contact dermatitis (e.g. in connection with p-aminobenzoate, very rarely with fluocinolone acetonide) secondary infection, dermal maceration, folliculitis, hypertrichosis, miliaria.

On application to large areas and/or under occlusion over long periods systemic effects are possible: suppression of endogenic corticosteroid synthesis, hypercorticosteroidism with oedema, manifestation of a previously latent diabetes mellitus, osteoporosis, and growth disturbances in children.

Interactions Not known so far

Overdosage On overdosage the incidence of the manifestations mentioned under "Side-effects" may increase.

Other points Synalar should not be used after the expiry date printed on the packing.

Presentations Synalar cream and Synalar ointment: Tubes of 15 g. Synalar lotion: Bottle of 20 ml. Synalar gel: Tube of 10 g.

Distributors and Manufacturers Protochemie AG, 8756 Mitlödi

Date of Information March 1992

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