GRÜNENTHAL

Synalar®-N Cream
Synalar®-N Ointment

Composition
Active substances
Synalar-N Cream and Synalar-N Ointment: fluocinolone acetonide, neomycin as neomycin sulphate.
Excipients
Synalar-N Cream: propylene glycol, preservatives: propyl hydroxybenzoate (E 216), methyl hydroxybenzoate (E 218); ointment excipients.
Synalar-N Ointment: propylene glycol, wool fat, ointment excipients.

Pharmaceutical Formulation and Quantities of Active Substance per Unit
Cream and ointment: fluocinolone acetonide 0.25 mg, neomycin 3.5 mg as neomycin sulphate, per 1 g.

Indications
Inflammatory, pruritic and allergic dermatoses superinfected with bacteria sensitive to neomycin.

Synalar-N Cream is particularly indicated in the acute and subacute stage, in weeping processes and greasy skin.

The non-aqueous Synalar-N Ointment is preferable for chronic and dry processes.

Dosage and Application
Apply sparingly to the affected areas once or twice daily.

The duration of treatment depends on the therapeutic success and usually does not exceed two to three weeks. If longer treatment is necessary, the physician should examine the patient's skin and pay attention to signs of changes in plasma hydrocortisone and decide whether or not to continue or repeat treatment.
Infants, toddlers and children: see "Warnings and Precautions".

Contraindications
Synalar-N is contraindicated in tuberculous and syphilitic skin diseases, vaccination reactions, primarily fungal, bacterial or viral skin diseases, and acne.

Ophthalmic application, perioral dermatitis and rosacea are contraindicated.

Synalar-N should not be applied to the auditory canal of patients with a perforated tympanic membrane (ototoxicity of neomycin).

On known intolerance to the active substance or an excipient of Synalar-N Cream or Ointment the respective preparation must not be used.

Warnings and Precautions
Occlusive dressings should not be used.

In order to ensure the greatest possible therapeutic safety, long-term treatment and application to large areas should be avoided, if possible, in patients in whom systemic corticoid treatment is contraindicated or must be carried out with special care. If it is carried out, the precautions applying to systemic corticoid treatment should be taken.

The application of potent corticoids in high doses or to extensive areas should only be carried out under regular medical supervision, particularly with regard to the suppression of endogenous corticosteroid production.
If possible, the preparation should not be applied continuously for more than 2-3 weeks.

If dermatosis does not adequately respond to treatment or even deteriorates, the diagnosis should be reviewed, particularly in the light of an allergy to one of the active substances (neomycin) or excipients (p-aminobenzoate) or an infection with resistant pathogens (e.g. fungi, etc.).

Corticosteroids may mask symptoms of an allergic dermal reaction to a component of the product.
Patients should be advised that the product is only to be used for their particular disease and it is not to be passed on to other people.

Attention must be paid to the possibility of impaired ulcer healing, particularly in the treatment of leg ulcers.

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

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

Interactions
None known.

Pregnancy/Lactation
Animal experiments (topical application of potent corticosteroids) showed evidence of reproduction toxicity. No animal studies have been carried out with Synalar-N, nor are sufficient data available on use during pregnancy. The potential risk for humans is not known.
The preparation must not be used during pregnancy, unless absolutely necessary. During pregnancy it should not be applied to large areas, in large quantities or for 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.

Effects on Road Safety and the Operation of Machinery.
Effects on road safety and the operation of machinery have not been investigated.

Side-effects
Skin
Uncommon (≥ 0.1 % - < 1 %)
Local side-effects such as dermal irritation, smarting, pruritus, dryness and hypersensitivity reactions to a component of the product may occur, particularly at the beginning of treatment.
On the topical application of Synalar-N 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 pigmentation, steroid acne, irritation, perioral dermatitis, contact dermatitis (e.g. to neomycin, p-aminobenzoate, very rarely to fluocinolone acetonide), dermal maceration, folliculitis, hypertrichosis, miliaria.

Rare: systemic complications such as
-endocrine disorders
On application to large areas and/or over long periods, systemic effects are possible: suppression of endogenous corticosteroid synthesis, hypercorticosteroidism with oedema, manifestation of previously latent diabetes mellitus,
-musculoskeletal diseases osteoporosis, and in children retarded growth.

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

Characteristics/Effects
- ATC Code D07CC02
Fluocinolone acetonide, the topical corticosteroid in Synalar-N, has a pronounced anti-inflammatory, anti-allergic and antipruritic effect. Topical corticosteroids are divided into four groups - very strong, strong, moderate and weak - and the fluorinated corticosteroid contained in Synalar-N is a strong topical corticosteroid preparation.

Synalar-N also contains the aminoglycoside neomycin, which has been used alone or combined with corticosteroids in topical dermatological therapy for more than 20 years. The action spectrum of neomycin covers Gram-positive and in particular Gram-negative pathogens.

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 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 urinary excretion of 17-ketosteroids of up to 1.3%. Consequently, the systemic effect of topical fluocinolone acetonide is negligible when used according to instructions. This has been confirmed by a large number of clinical studies.
The absorption of neomycin in an ointment base and aqueous solution applied to extensive areas was investigated in 16 patients. After one week's treatment 14 patients had not absorbed any neomycin. Two patients with 2nd and 3rd degree burns and a treated body area of 20% exhibited slight absorption with serum levels of less than 1 µg/ml.

Preclinical Data
Animal experiments with systemic corticosteroids have shown a teratogenic potential (in particular cleft palate).
Like other aminoglycoside antibiotics, neomycin causes ototoxic effects in rats on systemic prenatal exposure.

Other Points
- Shelf-life
Synalar-N should not be used after the expiry date printed on the pack.
Do not store above 30°C. Keep out of children's reach.

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

Packs
Synalar-N Cream 15 g
Synalar-N Ointment 15 g

Marketing Authorisation Holder
Grünenthal Pharma AG, 8756 Mitlödi

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