

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Synalar N Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fluocinolone Acetonide Ph. Eur 0.025% w/w

Neomycin Sulfate Ph. Eur 3250 IU/g

3 PHARMACEUTICAL FORM

Ointment

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Synalar-N combines the effective topical corticosteroid fluocinolone acetonide with an effective antibacterial agent neomycin sulfate.

It is indicated for inflammatory dermatoses including eczema, dermatitis, seborrhoea and intertrigo, where secondary bacterial infection is present or is likely to occur.

4.2 Posology and method of administration

A small quantity of Synalar N preparation is applied lightly to the affected area two or three times a day and massaged gently and thoroughly into the skin. These recommendations apply to both children and adults, including the elderly.

If an occlusive dressing is indicated, the affected area should first be thoroughly cleansed. The Synalar N preparation is then applied and covered with a suitable dressing.

Synalar N cream is particularly suitable for very inflamed or weeping surfaces and for flexures of the body, whilst Synalar N ointment is more suitable for dry scaly lesions.

Treatment should not normally be longer than seven days and it is preferable to identify the causative organism.

If used in childhood or on the face, courses should be limited to five days and occlusion in such cases should not be used.

4.3 Contraindications

Synalar N preparations are contra indicated in primary infections of the skin caused by bacteria, fungi or viruses and in rosacea, acne, perioral dermatitis, and napkin eruptions.

Synalar preparations are not advised in the treatment of children under one year of age. The eyes should be avoided.

Synalar N is contraindicated in those patients with a history of hypersensitivity to neomycin.

Topical neomycin preparations should not be applied to the external auditory canal of patients with perforated eardrums.

4.4 Special warnings and precautions for use

Long term continuous topical steroid therapy can produce local atrophic skin changes and dilation of the superficial blood vessels, particularly when occlusive dressings are used or where skin folds are involved.

Prolonged use of topical steroids or treatment of extensive areas, even without occlusion, can result in sufficient absorption of the steroid to produce the features of hypercorticalism and underlying adrenal suppression, especially in infants and children.

Long term use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

In the presence of a viral or fungal infection, the use of an appropriate agent should be instituted. If a favourable response does not occur promptly, Synalar N should be discontinued until the infection has been adequately controlled.

Because of the potential hazard of nephrotoxicity and ototoxicity associated with neomycin, prolonged use or use of large amounts of the product should be avoided in conditions where absorption of neomycin is possible. Care is particularly needed in elderly or renally-impaired patients.

These preparations are not for ophthalmic use.

Treatment should be discontinued if unfavourable reactions are seen.

The label will state strong steroid.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Fertility, Pregnancy and lactation

Pregnancy: There is inadequate evidence of safety in human pregnancy. Topical administration of steroids to pregnant animals can cause abnormalities of foetal development, including cleft palate and intrauterine retardation. There may therefore be a very small risk of such effects on the human foetus.

Lactation: Topical steroids should not be applied to the breasts prior to nursing. When topical steroid treatment is considered necessary during breast feeding, both the amount applied and the length of treatment should be minimised.

4.7 Effects on ability to drive and use machines

No precautions are necessary.

4.8 Undesirable effects

As with all topical steroids the occasional patient may develop an adverse reaction. Adverse reactions are listed by system organ class. The frequency of adverse reactions is not known (cannot be estimated from the available data).

Immune System Disorders

Local hypersensitivity reactions

Skin and Subcutaneous Tissue Disorders

Dermatitis

Perioral dermatitis

Acne or worsening of acne

Acne rosacea

Extensive treatment, particularly involving occlusive dressings or where skin folds are involved, can result in both local atrophic changes, such as striae, skin thinning and telangiectasia. Mild depigmentation, which may be reversible, hypertrichosis and irreversible striae.

Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)

Endocrine Disorders

Adrenal suppression.

General Disorders and Administration Site Conditions

Irritation at the site of application.

Infections and Infestations

The use of topical steroids on infected lesions, without the addition of appropriate anti-infective therapy, can result in the spread of opportunist infections.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Accidental ingestion:

The 30g tube of Synalar N contains 7.5mg of the steroid and 150mg of neomycin. No toxic effects are likely to occur even if the full contents of a 30g tube are ingested. Similarly the ingredients of the base are unlikely to have any toxic effect in the quantities in which they occur. Therefore no remedial action is required in the event of ingestion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, dermatological preparations; Corticosteroids, potent, combinations with antibiotics

ATC code: D07CC02

Fluocinolone acetonide is a synthetic anti-inflammatory corticosteroid. Its mechanisms of action are related to vasoconstriction and suppression of membrane permeability, mitotic activity, the immune response and release of inflammatory mediators.

Neomycin sulfate is an aminoglycoside antibacterial agent, which inhibits bacterial protein synthesis.

Synalar N Ointment is classed as a **potent** corticosteroid product.

5.2 Pharmacokinetic properties

The extent of percutaneous absorption of fluocinolone acetonide is determined by many factors including the vehicle, the integrity of the epidermal barrier and the use of occlusive dressings. Following absorption, fluocinolone acetonide is metabolised primarily in the liver and excreted by the kidneys.

Neomycin is not absorbed through intact skin. It is readily absorbed from large denuded, burned or granulating areas. Excretion is then as unchanged drug.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol Ph.Eur
Lanolin
Liquid Paraffin Ph.Eur
White Soft Paraffin BP

6.2 Incompatibilities

None known.

6.3 Shelf life

42 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Unlacquered, latex banded collapsible aluminium tube (30gm).

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

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6 August 2004

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