

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Synalar Cream 1 in 4 Dilution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fluocinolone Acetonide Ph. Eur. 0.00625% w/w

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Synalar Cream 1 in 4 dilution contains an effective topical steroid and is suitable for treating the milder forms of a wide variety of inflammatory, pruritic and allergic disorders of the skin. Synalar Cream 1 in 4 dilution is particularly suitable for topical applications in:

Eczema and dermatitis: atopic eczema, seborrhoeic eczema, discoid eczema, otitis externa, contact dermatitis, neurodermatitis.

Prurigo.

Psoriasis (excluding widespread plaque psoriasis). Lichen planus. Discoid lupus erythematosus.

Synalar Cream 1 in 4 dilution is indicated for milder forms of these conditions; for maintenance therapy when control has been achieved with Synalar for use under occlusive dressings; and for paediatric dermatology e.g. infantile eczema.

4.2 Posology and method of administration

Topical Administration

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

When an occlusive dressing is required, the affected area should first be thoroughly cleansed. Synalar Cream or ointment is then applied and covered with a suitable dressing. Occlusion should not be used for children or for the face. The cream dilution is particularly suitable for moist and weeping

surfaces and for flexures of the body. The ointment dilution is suitable for dry scaly lesions.

4.3 Contraindications

Synalar Cream 1 in 4 dilution is contra-indicated in primary infections of the skin caused by bacteria, fungi or viruses and in rosacea, acne, perioral dermatitis, anogenital pruritus and napkin eruption.

Synalar Cream 1 in 4 Dilution should not be used in patients that are hypersensitive to any of the ingredients.

Synalar preparations are not advised in the treatment of children under one year of age.

4.4 Special warnings and precautions for use

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

It is recommended that treatment on the face and for children should not normally be extended beyond five days, and occlusion in such cases should not be used.

When there is an infection associated with an inflammatory skin condition, Synalar should only be administered if adequate anti-infective cover is given.

When using topical steroids to treat psoriasis there are risks both of rebound relapse following the development of tolerance, and of generalised pustular psoriasis. Impairment of the barrier function of the skin may lead to local and systemic toxicity. Careful patient supervision is important.

Treatment should be discontinued if unfavourable reactions are seen.

The eyes should be avoided.

Some of the ingredients in the cream may cause a reaction:-

Cetostearyl alcohol - may cause local skin reactions (e.g. contact dermatitis).

Propylene glycol - may cause skin irritation.

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 corticosteroids to pregnant animals can cause abnormalities of foetal development, including cleft palate and intrauterine

growth 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 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.

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 national reporting system in the United Kingdom: Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

Accidental Ingestion:

Toxic effects are not likely to occur following accidental ingestion of the contents of a 50 g tube. If greater quantities are ingested and toxicity develops, symptomatic treatment should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

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.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol	EP
Benzyl Alcohol	BP
Cetostearyl Alcohol	EP
Liquid Paraffin	EP
Polysorbate 60	EP
Sorbitan Monostearate	BP
Purified Water	EP

Citric Acid

EP

6.2 Incompatibilities

None known

6.3 Shelf life

18 months

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

Internally lacquered aluminium tubes 50g

6.6 Special precautions for disposal

None stated

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 44095/0003

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
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03/03/2011

10 DATE OF REVISION OF THE TEXT

21/05/2015