

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Synalar Ointment 0.025% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fluocinolone Acetomde Ph. Eur. 0.025% w/w

3 PHARMACEUTICAL FORM

Ointment

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Synalar contains an effective topical steroid and is suitable for treating a wide variety of inflammatory, pruritic and allergic disorders of the skin. Synalar is particularly suitable for topical application 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.

4.2 Posology and method of administration

Adults (including the elderly) and children above one

A small quantity of the Synalar preparation is applied lightly to the affected area two or three times a day, and massaged gently and thoroughly into the skin. When an occlusive dressing is required, the affected area should first be thoroughly cleansed,

the Synalar preparations is then applied and covered with a suitable dressing. Occlusion should not be used for children or for the face. In some cases, the application of hot, moist compresses may be an advantage. The creams are particularly suitable for moist or weeping surfaces and for flexures of the body, the ointments are suitable for dry, scaly lesions.

4.3 Contraindications

Synalar is contraindicated in primary infections of the skin caused by bacteria, fungi or viruses and in rosacea, acne, perioral dermatitis, anogenital pruritus and napkin eruptions.

'Synalar' ointment 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:-

Lanolin - 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

None known

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 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 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: The 30g tube of Synalar contains 7.5mg of the steroid other tubes containing proportionately less. 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 accidental ingestion.

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

Fluocinolone acetonide is a drug on which extensive clinical experience has been obtained. All relevant information for the prescriber is provided elsewhere in the in the summary of product characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol Ph Eur
Lanolin
Citric acid Ph Eur
White soft paraffin BP

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

Collapsible aluminium tubes (30g and 100g)

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Reig Jofre UK Limited
10, The Barns
Farm Road
Caddsdow Industrial Park
Bideford
Devon EX39 3BT
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 44095/0005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/03/2011

10 DATE OF REVISION OF THE TEXT

01/07/2015