SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Synalar C Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fluocinolone Acetonide	Ph. Eur	0.025% w/w
Clioquinol	BP	3.000% w/w

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

‘Synalar’ C combines the effective topical corticosteroid ‘Synalar’ with the effective antibacterial and antifungal agent clinoquinol BP

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

4.2 Posology and method of administration

Topical Administration

A small quantity of the ‘Synalar’ C 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.

Treatment should not normally be for 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 should not be used.

If an occlusive dressing is indicated, the affected area is first thoroughly cleansed. The 'Synalar' C preparation is then applied and covered with a suitable dressing. 'Synalar' C Cream is particularly suitable for very inflamed or weeping surfaces and for flexures of the body, whilst 'Synalar' C ointment is more suitable for dry scaly lesions.

4.3 Contraindications

'Synalar' C 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' C preparations should not be used in patients that are hypersensitive to any of the ingredients.

'Synalar' C 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 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 infection, the use of an appropriate agent should be instituted. If a favourable response does not occur promptly 'Synalar' C should be discontinued until the infection has been adequately controlled.

Treatment should be discontinued if unfavourable reactions are seen. This product should not be used by patients with known iodine-sensitivity.

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

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

Methyl and propylparahydroxybenzoates - may cause local skin reactions (possibly delayed).

Propylene glycol - may cause skin irritation.

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 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 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.

Local application of clioquinol in creams or ointments may occasionally cause severe irritation, which may be less marked because of the fluocinolone acetonide.

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

Staining may occur due to breakdown of the clioquinol. A protective covering may be placed over the application to prevent staining of clothing or linen.

The eyes should be avoided.

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

The 15g tube of'Synalar' C contains 3.75mg of steroid and 0.45g of clinoquinol BP. No toxic effects are likely to occur even if the full contents of a tube are ingested. Similarly, the ingredients of the base are unlikely to have any toxic effects in the quantities in which they occur. Therefore, no remedial actions are required in the event of ingestion.

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.

Clioquinol is a broad spectrum anti-bacterial and anti-fungal agent. Its precise mechanism of action is unknown.

Synalar C Cream 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

Up to 4% clioquinol applied to the skin may be absorbed. Excretion is mainly as conjugated metabolites in the urine.

5.3 Preclinical safety data

Fluocinolone acetonide and clinoquinol are drugs on which extensive clinical experience has been obtained. All relevant information for the prescriber is provided elsewhere in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl Alcohol EP
Citric Acid EP
Disodium Edetate EP
Paraffin Liquid EP
Methyl Parahydroxybenzoate EP
Polysorbate 60EP
Propyl Parahydroxybenzoate EP
Propylene Glycol EP
Sorbitan Monostearate BP
Purified WaterEP

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

Internally lacquered collapsible aluminium tubes 15g

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Reig Jofre UK Limited
Unit 9A Caddsdown Business Support Centre
Caddsdown Industrial Park
Bideford
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EX39 3DX
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 44095/0007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/03/2011

10 DATE OF REVISION OF THE TEXT

18/07/2024