SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Metosyn FAPG Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient

Fluocinonide USP 0.050% w/w

3 PHARMACEUTICAL FORM

Cream for topical administration

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Metosyn is suitable for treating a wide variety of inflammatory, pruritic and allergic disorders of the skin. It is indicated for topical application in the following conditions:

Eczema and dermatitis; atopic eczema, seborrhoeic dermatitis, discoid eczema, contact dermatitis, neuro-dermatitis, prurigo, psoriasis (excluding widespread plaque psoriasis), lichen planus, discoid lupus erythematosus.

Metosyn FAPG cream may be used for wet or dry lesions.

4.2 Posology and method of administration

Adults

A small quantity of Metosyn' FAPG cream should be applied three to four times daily to the affected area and massaged well in.

Once improvement is apparent, usage may be reduced to twice or even once daily.

Children

Under one year: Metosyn preparations are not advised in the treatment of children under one year of age.

Over one year: As adult dose, however, it is recommended that treatment should not normally be extended beyond five days and occlusion in such cases should not be used.

Elderly

As adult dose.

It is recommended that Metosyn is used undiluted.

4.3 Contraindications

Metosyn is contraindicated in rosacea, acne and peri-oral dermatitis. As with all topical steroids, Metosyn is contra-indicated in tuberculous, syphilitic, fungal and viral infections of the skin. The product should not be used for napkin eruption or anogenital pruritus.

4.4 Special warnings and precautions for use

Long-term continuous topical steroid therapy can produce 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.

It is recommended that treatment on the face should not normally be extended beyond 5 days, and occlusion in such cases should not be used.

Where there is bacterial infection associated with an inflammatory skin condition, Metosyn should only be administered if adequate antibacterial cover is also given.

When using topical steroids to treat psoriasis there are risks 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 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.

Absorption is greatest where the skin is thin or raw.

The label will state strong steroid.

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 topical steroid treatment is considered necessary for other parts of the body, 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

With Metosyn side effects are extremely rare but, as with all topical steroids, the occasional patient may show an adverse reaction such as hypersensitivity. Irritation at the site of application may occur infrequently. 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, and systemic effects such as adrenal suppression.

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

The eyes should be avoided.

Local side effects include contact dermatitis, perioral dermatitis, acne, or worsening of acne or acne rosacea, mild depigmentation which may be reversible and hypertrichosis.

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). The frequency of this adverse reaction is not known (cannot be estimated from the available data).

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

Overdose (Symptoms, Emergency Procedures, Antidotes)

A 25g tube of Metosyn FAPG cream contains 12.5mg of fluocinonide. Toxic effects are not likely to occur following accidental ingestion. Similarly, the components of the vehicle, singly or collectively, have not been shown to produce toxic effects in these quantities.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, dermatological preparations; Corticosteroids, potent (group III).

ATC code: D07AC08

Fluocinonide 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.

Metosyn FAPG Cream is classed as a **potent** corticosteroid product.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

Fluocinonide is a drug 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

Citric Acid Ph Eur

1,2,6 Hexanetriol HSE

Polyethylene Glycol USNF

Stearyl Alcohol USP

Propylene Glycol Ph Eur

6.2 Incompatibilities

None Known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

Collapsible aluminium tube, coated internally with an epoxy resin lacquer and fitted with a white HDPE screw cap.

Pack sizes: 25 g and 100 g.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Use undiluted, as instructed by the prescriber.

7 MARKETING AUTHORISATION HOLDER

Reig Jofre UK Limited
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Totnes, Devon, TQ9 5NE,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 44095/0014

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/02/1989 / 08/12/2008

10 DATE OF REVISION OF THE TEXT

18/09/2025