

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CODERMO[®] 0.1% cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

1 g of cream contains 1 mg of Mometasone Furoate.

Excipients:

1 g of cream contains 80 mg of propylene glycol stearate.

For full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Cream.

White colored, homogenous cream with a characteristic odor.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

CODERMO[®] is indicated for treatment of psoriasis, eczematous dermatitis (atopic dermatitis) and inflammatory and pruritic lesions of all other dermatoses responsive to corticosteroids.

4.2. Posology and method of administration

Posology/frequency and duration of administration:

Method of administration:

A thin film of CODERMO[®] should be applied to the affected areas of the skin.

Frequency and duration of administration:

Once daily.

Additional information on special populations

Pediatric population:

In children the surface of the skin is larger than the adults to body mass ratios. Therefore they may be more susceptible to systemic effects of topical corticosteroids.

Use of topical corticosteroids in children or on the face should be limited to the least amount compatible with an effective therapeutic regimen and duration of treatment should be no more than 5 days. Continuous use of corticosteroids may affect the growth and development of children.

It is not recommended for use in infants and young children unless absolutely necessary.

Renal/liver failure:

No dosage adjustment is required.

Geriatric population:

No dose adjustment is required.

4.3. Contraindications

CODERMO[®] is contraindicated in facial rosacea, acne vulgaris, perioral dermatitis, perianal and genital pruritis, napkin eruptions, bacterial (e.g. impetigo), viral (e.g. herpes simplex, herpes zoster and chickenpox verrucae) and fungal (e.g. candida or dermatophyte) infections,

varicella, tuberculosis, syphilis or postvaccine reactions. CODERMO® should not be used in patients who are sensitive to mometasone furoate or to other corticosteroids

4.4. Special warnings and precautions for use

If irritation or sensitisation develop with the use of CODERMO®, treatment should be withdrawn and appropriate therapy instituted.

Should an infection develop, use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled.

Local and systemic toxicity is common especially following long continued use on large areas of damaged skin, in flexures and with polythene occlusion. If used in childhood, or on the face, courses should be limited to 5 days and occlusion should not be used. Long term continuous therapy should be avoided in all patients irrespective of age.

Systemic absorption of potent topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria.

Hypothalamic-pituitary-adrenal (HPA) axis function is rapidly improved following discontinuation of the drug. Symptoms associated with discontinuation of drug may be seen rarely. In such cases, systemic corticosteroid replacement therapy may be instituted.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Pediatric patients may be more susceptible to HPA axis suppression and Cushing syndrome than the adults, due to their larger skin surface to body mass ratios. In children, the use of topical corticosteroids should be limited to the least amount compatible with an effective therapeutic regimen. Continuous use of corticosteroids may affect the growth and development of children.

CODERMO® is not for ophthalmic use.

Patients should be aware that:

1. This medicine is developed for topical use in skin diseases. Contact with the eyes should be avoided.
2. This medicine should not be used for any other disease than the disease that the doctor recommends.
3. Unless otherwise prescribed by the doctor, the affected part of the skin should not be covered by a bandage or any other dressing.

CODERMO® contains propylene glycol stearate that may cause irritation on the skin.

4.5. Interaction with other medicinal products and other forms of interaction

There is no known interaction

4.6. Pregnancy and lactation

General Recommendation

Pregnancy category: C

Women with childbearing potential / Contraception:

There are no available data showing the effect of mometasone furoate on women with childbearing potential.

Pregnancy

There are no adequate data on the use of CODERMO® in pregnant women. Animal studies demonstrated evidence of reproductive toxicity. Potential risk on humans is not known. CODERMO® should not be used in pregnancy unless it is necessary.

There are no studies showing the teratogenic effects of locally applied corticosteroids in pregnant women. Therefore such medicines should be used in pregnancy considering its benefits and risk. Application on large body surfaces or over a prolonged period should be avoided.

There are limited information on the safety of CODERMO® in pregnant women. Topical corticosteroids should be used in pregnant women only if the potential benefit outweighs the potential risks. Drugs included in this class should not be used in large quantities and for long time.

Breastfeeding

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. CODERMO® should be administered to nursing mothers only after careful consideration of the benefit/risk relationship.

Reproduction / Fertility

Genetic toxicity studies conducted with mometasone furoate (Ames test, mouse lymphoma assay and micronucleus test) did not show a mutagenic potential.

4.7. Effects on ability to drive and use machines

It has no effect on the ability to drive and use machines.

4.8. Undesirable effects

Undesirable effects frequencies are defined as: very common ($\geq 1/10$); common ($\geq 1/100$ and $< 1/10$); uncommon ($\geq 1/1.000$ and $< 1/100$); rare ($\geq 1/10.000$ and $< 1/1.000$); very rare ($< 1/10.000$), not known (cannot be estimated from the available data).

Skin and subcutaneous tissue disorders

Rare: Local adverse reactions such as irritation, hypertrichosis, hypopigmentation, perioral pigmentation, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria may be seen.

Very rare: Local adverse reactions such as Paresthesia, itching and skin atrophy, abscess, burning, exacerbation of the disease, dryness of the skin, erythema, frunculosis and acne may be seen.

CONSULT YOUR DOCTOR IF ANY UNDESIRABLE EFFECT OCCURS.

4.9. Overdose

No cases of overdose have been reported with the use of CODERMO®.

Excessive, prolonged use of topical corticosteroids can suppress hypothalamic-pituitary-adrenal function resulting in secondary adrenal insufficiency.

Necessary symptomatic treatment should be applied in case of overdose. Acute hypercorticism symptoms are almost reversible. Electrolyte imbalance is treated when required. In cases of chronic toxicity, tapering of corticosteroids is recommended.

Excessive use of topical corticosteroids may cause systemic side effects following absorption. In this case the treatment should be discontinued.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Potent corticosteroids

ATC code: D07AC13

Mometasone furoate is a corticosteroid with marked anti-inflammatory, antipruritic and anti-psoriatic activity.

Corticosteroids are steroid hormones and their synthetic analogues secreted from the kidneys. They are used at pharmacological doses to provide anti-inflammatory activity or to suppress immunity. Topically applied corticosteroids are effective in the treatment of dermatoses responsive to corticosteroids due to their anti-inflammatory, antipruritic properties.

Topical corticosteroids can be absorbed from normal or damaged skin. The rate of cutaneous absorption depends on the liquids used in the preparation, the integrity of the epidermis and the application of occlusion. Cutaneous absorption increases in case of occlusion and inflammatory conditions.

5.2. Pharmacokinetic properties

General properties

Studies on the effects of mometasone furoate applied to the affected skin on the hypothalamus-hypophysis-surrenal axis showed that plasma cortisol levels were not significantly altered.

Absorption: Systemic absorption following topical application of mometasone furoate cream 0.1% is minimal. In man, approximately 0.4% of the applied dose is absorbed.

Distribution: Topically used corticosteroids are bound at varying levels to plasma proteins, following cutaneous absorption, through the same pharmacokinetic procedures as systemic corticosteroids.

Biotransformation: Mometasone furoate is mainly metabolized in liver.

Elimination: Excreted in urine via the kidneys.

Linearity / non-linearity: There are no studies performed.

5.3. Preclinical safety data

Genetic toxicity studies conducted with mometasone furoate (Ames test, mouse lymphoma assay and micronucleus test) did not show a mutagenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hexylene glycol

Propylene glycol stearate

Promulgen G

Aluminium starch octenylsuccinate

White wax

White soft paraffin

Titanium dioxide

Deionized water

Phosphoric acid

6.2. Incompatibilities

None known

6.3 Shelf-life

36 months

6.4 Special precautions for storage

Store at room temperature below 25°C and do not freeze.

6.5 Nature and contents of container

Marketed in an aluminum tube with a plastic cap in a box.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any unused medicinal product or waste material should be disposed of in accordance with the “Regulation on Medical Waste” and “Regulation on the Control of Packaging and Packaging Waste”.

7. MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

207/95

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorization: 03.04.2006

Date of renewal: ----

10. DATA OF REVISION OF THE TEXT

14/12/2013