SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Modrasone Ointment.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Alclometasone Dipropionate 0.05% w/w

Excipients with known effect:
Propylene Glycol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Modrasone is a non-fluorinated topically active synthetic corticosteroid indicated for the treatment of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

4.2 Posology and method of administration

For topical administration

For adults and children, apply a thin film of Modrasone Ointment to the affected area two or three times daily or as directed by the doctor.
Massage gently into the skin until the medication disappears.

4.3 Contraindications

Hypersensitivity to any of the ingredients; rosacea; acne and perioral dermatitis. Tuberculous and viral lesions or the skin, particularly Herpes Simplex; Vaccinia: varicella.
Modrasone should not be used in fungal or bacterial skin infections.

4.4 Special warnings and precautions for use

The label will state moderate steroid.

As with all topical steroids, long term continuous therapy should be avoided where possible, particularly in infants and children as adrenal suppression may occur even without occlusion. In infants the napkin may act as an occlusive dressing and thus increase absorption.

For dermatologic use only.

If irritation or sensitization develops with the use of Modrasone, treatment should be discontinued and appropriate therapy instituted.

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

Systemic absorption of topical corticosteroids may be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.

Modrasone ointment contains 20 mg propylene glycol per gram of ointment. Propylene glycol may cause skin irritation.

<u>Paediatric Use</u>:

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a larger skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels, and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches, and bilateral papilledema.

This medicine must not be used in babies less than 4 weeks old with open wounds or large areas of broken or damaged skin (such as burns).

Modrasone products are not for ophthalmic use.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Topical steroid withdrawal syndrome

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 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.

4.5 Interaction with other medicinal products and other forms of interaction

None Known.

4.6 Fertility, Pregnancy and lactation

Pregnancy
Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Drugs of this class should not be used extensively in large amounts for prolonged periods of time in pregnant patients.

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

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Adverse reactions reported rarely with alclometasone dipropionate are itching, burning, erythema, dryness, irritation, and papular rashes.

Other local adverse reactions associated with topical corticosteroids, especially under occlusive dressings, include folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, skin maceration, secondary infection, skin atrophy, striae and miliaria.

Excessive prolonged use may result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face.

Skin and subcutaneous tissue disorders

Not known (cannot be estimated from available data): 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)

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 (website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store).

4.9 Overdose

Acute overdosage with dermatologic application of corticosteroids is unlikely and would not be expected to lead to a life-threatening situation.

Symptoms: Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency, and produce manifestations of hypercorticism, including Cushing's disease.

Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised.

The steroid content is so low as to have little or no effect in the unlikely event of accidental oral ingestion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D07AB10

Alclometasone dipropionate is a non-fluorinated, topically active synthetic corticosteroid. Alclometasone dipropionate suppresses local inflammation at doses producing minimal systemic effects. Studies have shown alclometasone dipropionate to be approximately 2/3 as potent as betamethasone valerate and 60 x as potent as hydrocortisone. Modrasone is classed as a moderately potent corticosteroid.

5.2 Pharmacokinetic properties

Not applicable in view of topical action and application.

5.3 Preclinical safety data

Modrasone Ointment appears to be a relatively non-toxic and non-irritating drug product that produces no unusual or unexpected teratologic effects in laboratory animals. A wide margin of safety was demonstrated in all species studied. Acute oral and intraperitoneal doses more than 3,000 times the proposed topical human dose were without any toxicologically significant effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hexylene glycol
Propylene glycol monostearate
White Beeswax
White soft paraffin.

6.2 Incompatibilities

None known.

6.3 Shelf life

60 months.

6.4 Special precautions for storage

Store below 25ºC.

6.5 Nature and contents of the container

Aluminium tubes with white LDPE caps.
Pack sizes 5g, l5g, 30g. 50g.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 35533/0096

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26 April 1995

10 DATE OF REVISION OF THE TEXT

22/07/2024