Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Modrasone Cream 0.05% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Alclometasone Dipropionate 0.05% w/w

Excipients with known effect:
25% w/w propylene glycol, 0.1% w/w chlorocresol and 7.2% w/w cetostearyl alcohol.

For a full list of excipients see Section 6.1.

3 PHARMACEUTICAL FORM

Cream
A smooth, white to off-white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Modrasone Cream is indicated in adults and children for the treatment of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

4.2 Posology and method of administration

Posology

Adults (including the elderly) and children
A thin film of Modrasone Cream should be applied to the affected area two or three times daily or as directed by the physician. Massage gently into the skin until the medication disappears.

Method of administration
For topical administration.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Use in the presence of untreated infections of bacterial, viral tuberculous or fungal origin.
Use in acne rosacea, acne vulgaris or in perioral dermatoses.

4.4 Special warnings and precautions for use

For dermatologic use only.

Long term continuous therapy should be avoided in all patients irrespective of age due to increased risk of adrenocortical suppression. Continuous treatment for longer than two weeks should be avoided in children.
Prolonged use of uninterrupted occlusion or use with extensive occlusive dressings may supress adrenocortical function.

If irritation or sensitization develops with the use of Modrasone products, 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.

There have been a few reports in the literature of the development of cataracts in patients who have been using corticosteroids for prolonged periods of time. Although it is not possible to rule out systemic corticosteroids as a known factor, prescribers should be aware of the possible role of corticosteroids in cataract development.

In the presence of infection, an appropriate antifungal or antibacterial agent should be administered. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection has been controlled adequately.

Paediatric population:

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.

Modrasone products are not for ophthalmic use.

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.

Fertility
No fertility data is available.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Local
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.

Continuous application without interruption will result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, moderately potent (group II),
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 times as potent as betamethasone valerate and 60 x as potent as hydrocortisone.

5.2 Pharmacokinetic properties

Not applicable in view of topical action and application.

5.3 Preclinical safety data

Modrasone Cream 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

Propylene glycol
White soft paraffin
Cetostearyl alcohol
Glyceryl stearate PEG 100 stearate
Macrogol Cetostearyl Ether
Sodium Dihydrogen Phosphate Dihydrate
Chlorocresol
Phosphoric acid, concentrated
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tubes with white LDPE caps. Pack sizes: 5g, 15g, 30g, 50g.

Not all pack sizes may be marketed.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Morningside Healthcare (Malta) Limited
93 Mill Street
Qormi QRM 3102
Malta

8 MARKETING AUTHORISATION NUMBER

PA23142/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 August 1984

Date of last renewal: 03 June 2007

10 DATE OF REVISION OF THE TEXT

January 2024