**DERMANEX CREAM**
**(Mometasone Furoate Cream IP 0.1% W/W)**

## COMPOSITION
Mometasone Furoate I.P…… 0.1% w/w
Cream base…… q.s.

## INDICATIONS
Steroid responsive dermatitis, eczema, or atopic dermatitis

## POSOLOGY AND METHOD OF ADMINISTRATION
*Adults, including elderly patients and Children:* A thin film of Mometasone Furoate Cream should be applied to the affected areas of skin once daily.

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.

## CONTRAINDICATIONS
Mometasone Furoate is contraindicated in facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritis, napkin eruptions, bacterial (e.g. impetigo, pyodermas), viral (e.g. herpes simplex, herpes zoster and chickenpox verrucae vulgares, condylomata acuminata, molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections, varicella, tuberculosis, syphilis or postvaccine reactions. Mometasone Furoate should not be used on wounds or on skin which is ulcerated. Mometasone Furoate should not be used in patients who are sensitive to mometasone furoate or to other corticosteroids or to any of the excipients.

## SPECIAL WARNINGS AND PRECAUTIONS FOR USE
If irritation or sensitisation develop with the use of Mometasone Furoate, treatment should be withdrawn and appropriate therapy instituted.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 favourable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled.

Systemic absorption of topical corticosteriods can produce reversible hypothalamic-pituitary adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glycosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients applying a topical steroid to a large surface area or areas under occlusion should be evaluated periodically for evidence of HPA axis suppression.

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 systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. As the safety and efficacy of Mometasone

Furoate in paediatric patients below 2 years of age have not been established, its use in this age group is not recommended.

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, occlusion should not be used. If used 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.

Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of centralised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important.

As with all potent topical glucocorticoids, avoid sudden discontinuation of treatment. When long term topical treatment with potent glucocorticoids is stopped, a rebound phenomenon can develop which takes the form of a dermatitis with intense redness, stinging and burning. This can be prevented by slow reduction of the treatment, for instance continue treatment on an intermittent basis before discontinuing treatment.

Glucocorticoids can change the appearance of some lesions and make it difficult to establish an adequate diagnosis and can also delay the healing.

Mometasone Furoate topical preparations are not for ophthalmic use, including the eyelids, because of the very rare risk of glaucoma simplex or subcapsular cataract.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

**DRUG INTERACTION**

None stated

**PREGNANCY AND LACTATION**

Pregnancy

During pregnancy treatment with Mometasone Furoate should be performed only on the physician's order. Then however, the application on large body surface areas or over a prolonged period should be avoided. There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. There are no adequate and well controlled studies with Mometasone Furoate in pregnant women and therefore the risk of such effects to the human foetus is unknown. However as with all topically applied glucocorticoids, the possibility that foetal growth may be affected by glucocorticoid passage through the placental barrier should be considered. There may therefore be a very small risk of such effects in the human foetus. Like other topically applied glucocorticoids, Mometasone Furoate should be used in

pregnant women only if the potential benefit justifies the potential risk to the mother or the foetus.

Lactation
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Mometasone Furoate should be administered to nursing mothers only after careful consideration of the benefit/risk relationship. If treatment with higher doses or long term application is indicated, breastfeeding should be discontinued.

**EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**
None stated.

**UNDESIRABLE EFFECTS**

**Table 1: Treatment-related adverse reactions reported with Elocon by body system and frequency**

Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000); very rare (<1/10 000,); not known (cannot be estimated from available data)

| | |
|---|---|
| **Infections and infestations** | |
| Not known | Infection, furuncle |
| Very rare | Folliculitis |
| **Nervous system disorders** | |
| Not known | Paraesthesia, |
| Very rare | Burning sensation |
| **Skin and subcutaneous tissue disorders** | |
| Not known | Dermatitis contact, skin hypopigmentation, hypertrichosis, skin striae, dermatitis acneiform, skin atrophy |
| Very rare | Pruritus |
| **General disorders and administration site conditions** Not known | Application site pain, application site reactions |
| **Eye disorders** | |
| Not Known | Vision blurred |

Local adverse reactions reported infrequently with topical dermatalogic corticosteroids include: skin dryness, irritation, dermatitis, perioral dermatitis, maceration of the skin, miliaria and telangiectasiae.

Paediatric patients may demonstrate greater susceptibility to topical corticosteroidinduced Hypothalamicpituitaryadrenal axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Chronic corticosteroids therapy may interfere with the growth and development of children.

**OVERDOSE**
Excessive, prolonged use of topical corticosteroids can suppress hypothalamic-pituitary-adrenal function resulting in secondary adrenal insufficiency which is usually reversible.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application or to substitute a less potent steroid.
The steroid content of each container is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

## PHARMACOLOGICAL PROPERTIES

### Pharmacodynamic properties
Pharmacotherapeutic group: Mometasone, ATC code: D07AC13

Mometasone furoate exhibits marked anti-inflammatory activity and marked antipsoriatic activity in standard animal predictive models.

In the croton oil assay in mice, mometasone was equipotent to betamethasone valerate after single application and about 8 times as potent after five applications.

In guinea pigs, mometasone was approximately twice as potent as betamethasone valerate in reducing m.ovalisinduced epidermal acanthosis (i.e. antipsoriatic activity) after 14 applications.

### Pharmacokinetic properties
Pharmacokinetic studies have indicated that systemic absorption following topical application of mometasone furoate cream 0.1% is minimal, approximately 0.4% of the applied dose in man, the majority of which is excreted within 72 hours following application. Characterisation of metabolites was not feasible owing to the small amounts present in plasma and excreta.

### Preclinical safety data
There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## EXPIRY DATE
Do not use later than the date of expiry

## PACKAGING INFORMATION
DERMANEX is available in Tube pack of 10gm and 30gm

## STORAGE AND HANDLING INSTRUCTIONS
Store at a temperature below 25°C. Protected from light. Do not Freeze

## MARKETED BY
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TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

**IN/DERMANEX CREAM 0.1%W/W/JUN-18/02/PI**