SUMMARY OF PRODUCT CHARACTERISTICS

Elocom® Lotion

1 NAME OF THE MEDICINAL PRODUCT

Elocom® Lotion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mometasone furoate 0.1% w/w

Excipient with known effect:

Propylene glycol 30.0% w/w

For full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Lotion

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Elocom Lotion is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, such as psoriasis and atopic dermatitis.

4.2 Posology and method of administration

Apply a few drops of mometasone furoate lotion to the affected skin areas once daily.

Pediatrics population

As the safety and efficacy of Elocom in pediatric patients below 2 years of age have not been established, its use in this age group is not recommended.

4.3 Contraindications

Elocom Lotion is contraindicated in skin atrophy, 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 of the skin or scalp. Elocom should not be used on wounds or on skin which is ulcerated**.** Elocom Lotion should not be used in patients who are sensitive to mometasone furoate or to other corticosteroids or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If irritation or sensitisation develop with the use of Elocom, treatment should be withdrawn and appropriate therapy instituted.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 glucosuria 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 Elocom in pediatric 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. If used in childhood, occlusion should not be used and courses should be limited to 5 days. 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 centralized 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.

Elocom Lotion contains propylene glycol which may cause skin irritation.

Care must be taken to keep the preparation away from the eyes. Elocom 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.

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.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy

During pregnancy treatment with Elocom 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 intra-uterine growth retardation.

There are no adequate and well-controlled studies with Elocom 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, Elocom 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. Elocom 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, breast-feeding should be discontinued.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Table 1: Treatment-related adverse reactions reported with Elocom 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 (see also section 4.4)

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

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal 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.

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.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

4.9 Overdose

Excessive prolonged use of topical corticosteroids can suppress hypothalamic- pituitary-adrenal function resulting in secondary adrenal insufficiency which is usually reversible. In such cases appropriate symptomatic treatment is indicated.

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mometasone, ATC code: D07AC13

Mometasone furoate exhibits marked anti-inflammatory activity and marked anti-psoriatic 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.ovalis-induced epidermal acanthosis (i.e. anti-psoriatic activity) after 14 applications.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have indicated that systemic absorption following topical application of mometasone furoate 0.1% ointment is minimal, approximately 0.7% 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. Minimal absorption would be anticipated with the lotion formulation.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of this SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl alcohol;
Propylene glycol;
Hydroxypropyl cellulose;
Sodium dihydrogen phosphate dihydrate;
Phosphoric acid;
Purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the package

6.4 Special precautions for storage

Store not above 25°C.
Can be used for up to 3 months after first opening.

6.5 Nature and contents of container

20ml LDPE bottles.

6.6 Special precautions for disposal and other handling

Not applicable.

7 MANUFACTURER

Merck Sharp & Dohme Corp., New-Jersey, USA.

8. LICENSE HOLDER

Merck Sharp & Dohme (Israel-1996) Company Ltd, P.O.B. 7121 Petach-Tiqva 49170.

9. REGISTRATION NUMBER 137-48-28715

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