Summary of Product Characteristics

Elocom® Cream
Elocom® Ointment

1. NAME OF THE MEDICINAL PRODUCT

Elocom® Cream

Elocom® Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Mometasone furoate 0.1% w/w

Elocom Ointment- Excipients with known effect:
Propylene glycol stearate 2.0% w/w
For full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Cream

Ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Elocom is indicated for the 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 thin film of mometasone furoate cream or ointment to the affected skin areas once daily.
The duration of treatment of topical corticosteroids on the face should be no more than 5 days.

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 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 post-vaccine reactions. Elocom should not be used on wounds or on skin which is ulcerated. Elocom 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If irritation or sensitisation develop with the use of Elocom, treatment should be withdrawn and appropriate therapy instituted.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-pituitaryadrenal (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.

Paediatric 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 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.

Elocom Ointment contains propylene glycol which may cause skin irritation.

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.

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 a 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 stated

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 stated.

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 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).
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.

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 is classed as a potent corticosteroid (group III).

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% is minimal, Elocom Cream - approximately 0.4% of the applied dose in man, Elocom Ointment - approximately 0.7% of the applied dose in man, the majority of which is excreted within 72 hours following application. Characterization of metabolites was not feasible owing to the small amounts present in plasma and excreta.

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 the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Elocom Cream:
White soft paraffin
Hexylene glycol
Aluminium starch octenylsuccinate
White beeswax
Purified water
Hydrogenated soybean lecithin
Titanium dioxide
Phosphoric acid

Elocom Ointment:
White soft paraffin
Hexylene glycol
White beeswax
Purified water
Propylene glycol stearate
Phosphoric acid

6.2 Incompatibilities

None known.

6.3 Shelf life
The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage
Store not above 25°C.
Elocom Cream - after first opening, can be used for 3 months.
Elocom Ointment - after first opening, can be used for 1 month.

6.5 Nature and contents of containers
Elocom Cream: 15 gram, epoxy lined aluminum tubes.
Elocom Ointment: 15 gram, aluminium tube.

6.6 Special precautions for disposal and other handling
Not applicable.

7. MANUFACTURER
Organon LLC, NJ USA

8. LICENSE HOLDER AND ADDRESS
Organon Pharma Israel Ltd., 1 Atir Yeda, Kfar Saba

9. REGISTRATION NUMBER
Elocom Cream: 060.05.26514
Elocom Ointment: 060.06.26513

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