SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Elocon 0.1% w/w Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mometasone Furoate 0.1% w/w (equivalent to 1.0mg/g)

Propylene glycol stearate 2.0% w/w (equivalent to 20mg/g)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ointment
A white to off-white, opaque ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Elocon Ointment is indicated for the topical management of corticosteroid responsive dermatoses.

4.2 Posology and method of administration

Adults, including elderly patients and Children : A thin film should be applied to the affected areas of skin once daily.

Use of topical corticosteroids in children should be limited to the least amount compatible with an effective therapeutic regimen. Safe use in children for more than 6 weeks has not been established. There are limited data in children under 2 years.

4.3 Contraindications

Use in acne vulgaris, rosacea, skin atrophy, perioral dermatoses perianal and genital pruritus, napkin eruptions, varicella, tuberculosis, syphilis or post-vaccine reactions or in widespread plaque psoriasis.

Use in the presence of untreated infections of: bacterial (e.g. impetigo, pyodermas); viral (e.g. herpes simplex, herpes zoster, chickenpox, verrucae vulgares, condylomata acuminata, molluscum contagiosum); parasitical and fungal (e.g. candida or dermatophyte) or tuberculousorigin, or post-vaccinal reactions. Elocon should not be used on wounds or on skin which is ulcerated.

Dermatoses in children under one year of age, including dermatitis and napkin eruptions.

Hypersensitivity to the preparation.

4.4 Special warnings and precautions for use

Local and systemic toxicity, including suppression of adrenocortical function may occur especially following prolonged continued use on large areas of damaged skin, in flexures and with occlusion (including napkin).

Elocon may be used with caution in paediatric patients 2 years of age or older, although the safety and efficacy of the use of Elocon for longer than 3 weeks have not been established. As the safety and efficacy of Elocon in paediatric patients below 2 years of age have not been established, its use in this age group is not recommended.

Chronic corticosteroid therapy may interfere with the growth and development of children. If used in children, or 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.

If irritation or sensitisation develops, treatment should be withdrawn and appropriate therapy instituted. Should an infection develop, use of an appropriate anti-infective agent should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled.

Continued use in psoriasis may lead to generalisation, excessive systemic absorption and rebound relapse on cessation of use. Careful patient supervision is necessary.
If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result.

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.

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

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.

Elocon Ointment contains propylene glycol which may cause skin irritation.

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

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Animal studies have shown teratogenic effects. The safe use of Elocon during pregnancy and lactation has not been established.

During pregnancy and lactation, treatment with Elocon 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. As with all topically applied glucocorticoids in pregnant women, the possibility that foetal growth may be affected by glucocorticoid passage through the placental barrier should be considered. Glucocorticoids are excreted into the breast milk. 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 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 the 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 disorder	
Not known	Blurred vision

Local side effects also include tingling and stinging.

Additional local side effects reported infrequently when topical dermatological corticosteroids have been used as recommended include: burning, irritation, dryness, hypertrichosis, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae, miliaria.

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

Any of the side effects which have been reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in paediatric patients.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

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

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: corticosteroids, potent (group III)
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% 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.

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

Hexylene glycol
Phosphoric acid
Propylene glycolstearate
White beeswax
White soft paraffin
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

5, 15, 30, 45 and 100g aluminium tubes with low density polyethylene cap or laminated tubes with high density polyethylene head and polypropylene cap.
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

Merck Sharp & Dohme Ireland (Human Health) Limited
Red Oak North
South County Business Park
Leopardstown
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 1286/35/2

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th December 1993

Date of last renewal: 22nd January 2007

10 DATE OF REVISION OF THE TEXT

September 2017