Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Elocon 0.1% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Elocon cream contains hydrogenated soya phosphatidylcholine (15mg/g).

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream

White to off-white smooth homogenous cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Elocon Cream 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 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), tuberculous or parasitical and fungal origin (e.g. candida or dermatophyte) varicella, syphilis or post-vaccinal reactions.

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

Hypersensitivity to the preparation.

Elocon should not be used on wounds or on skin which is ulcerated.

4.4 Special warnings and precautions for use

Local and systemictoxicity, includingsuppression of adrenocortical function mayoccur especiallyfollowingprolonged continueduse on large areas, in flexures andwith occlusion (includingnapkin).

Chronic corticosteroid therapymayinterferewith thegrowth and development of children.

If usedin children, oron the face, courses should belimited to 5 days andocclusion shouldnot beused. Longterm continuous therapyshould be avoided in allpatients, irrespectiveof age.

Elocon maybeusedwith caution in paediatricpatients 2 years of ageor older, although the safetyand efficacyof theuse of Elocon for longer than 3 weeks havenot been established.As the safetyand efficacyof Elocon in paediatricpatients below 2 years of agehavenot been established,its use in this agegroupis notrecommended.

Topical steroids maybehazardous in psoriasisforanumberof reasonsincludingrebound relapses followingdevelopment of tolerance, risk of centralised pustularpsoriasisand development of local or systemictoxicitydueto impaired barrier function of the skin. If used in psoriasiscareful patient supervision is important.

If irritation or sensitisation develop, treatment should be withdrawn and appropriate therapy instituted. Should an infection develop, useof an appropriate anti-infective agent should be instituted. If afavourable response does not occurpromptly, the corticosteroid should be discontinued until theinfection is adequatelycontrolled.

Continued usein psoriasis maylead to generalisation, excessivesystemic absorption and rebound relapseon cessation of use. Careful patient supervision is necessary. If applied to the eyelids, careis needed to ensurethat the preparation does not enterthe eye, as glaucoma might result.

Anyof theside effects that are reported followingsystemicuse of corticosteroids, including adrenal suppression, mayalso occurwith topical corticosteroids, especiallyin infants and children.

Visual disturbancemaybe reported with systemic and topical (includingintranasal, inhaled and intraocular) corticosteroid use. If apatient presents with symptoms such as blurred vision orothervisual disturbances, the patient should be considered for referral to an ophthalmologistfor evaluation of possible causes ofvisual disturbances which mayinclude cataract, glaucoma or rarediseases such as central serous chorioretinopathy(CSCR) which havebeen reported after useof systemic and topical corticosteroids.

As with allpotent topical glucocorticoids, avoid sudden discontinuation oftreatment. When longterm topical treatment with potent glucocorticoids is stopped, a rebound phenomenon can develop which takes the form of adermatitis with intense redness, stingingand burning. This can beprevented byslow reduction ofthe treatment, forinstance continuetreatment on an intermittent basis beforediscontinuingtreatment.

Glucocorticoids can changethe appearanceof somelesions and makeitdifficult to establish an adequate diagnosis and can also delaythe healing.

Elocon topical preparations arenot forophthalmicuse,includingthe eyelids, because of the veryrarerisk of glaucoma simplexor subcapsular cataract.

Eloconcreammaycontaintraceamountsofsoya. Ifyouareallergictosoya,donotusethis medicinal product.

4.5 Interaction with other medicinal products and other forms of interactions

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 bybodysystem and frequency Verycommon (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000); veryrare(<1/10 000);not known (cannot be estimated from the available data)	
Infectionsandinfestations	
Not known	Infection, furuncle
Veryrare	Folliculitis
Nervous systemdisorders	
Not known	Paraesthesia
Veryrare	Burningsensation
Skinandsubcutaneous tissuedisorders	
Not known	Dermatitis contact, skin hypopigmentation, hypertrichosis, skin striae, dermatitis acneiform, skin atrophy
Veryrare	Pruritus
General disorders andadministrationsite conditions	
Not known	Application site pain, application site reactions
Eyedisorder	
Not known	Blurred vision

Local side effects also include tinglingand stinging.

Additional local side effects reported infrequentlywhen topical dermatological corticosteroids havebeen used as recommended include: burning, irritation, dryness, hypertrichosis, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration ofthe skin, secondaryinfection, striae, miliaria.

Continuous application withoutinterruption willresultin local atrophyof theskin,striae and superficial vasculardilatation, particularlyon the face.

Anyof theside effects which havebeen reported followingsystemicuse of corticosteroids, includingadrenal suppression, mayalso occurwith topical corticosteroids, especiallyin paediatricpatients.

Reportingofsuspected adverse reactions
Reportingsuspected adverse reactions afterauthorisation of the medicinalproduct is important. It allows continued monitoringof the benefit/riskbalance of the medicinalproduct. Healthcare professionals are asked to reportanysuspected adverse reactions via HPRAPharmacovigilance, EarlsfortTerrace, 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 (groupIII)
ATC-code: D07AC13

Mometasone furoate exhibits marked anti-inflammatoryactivityand marked anti-psoriatic activityin standard animal predictive models.

In the croton oil assayin mice, mometasonewas equipotent to betamethasonevalerate after single application and about 8 times as potent after five applications.

In guineapigs, mometasonewas approximatelytwice as potent as betamethasonevalerate in reducingm.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
Hydrogenated soya phosphatidylcholine
Titanium dioxide
Aluminium starch octenylsuccinate
White beeswax
White soft paraffin
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

5g, 15g, 20g, 30g, 50g and 100g aluminium tubes with high density closures.

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

Organon Pharma (Ireland) Limited
2 Dublin Landings
North Wall Quay - North Dock
Dublin
D01 V4A3
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23198/010/001

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

October 2021