

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **Elocon® Scalp Lotion**

### **1 NAME OF THE MEDICINAL PRODUCT**

Elocon® Scalp Lotion

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Mometasone Furoate 0.1% w/w

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**

Elocon Scalp Lotion is indicated for the treatment of inflammatory and pruritic manifestations of psoriasis and seborrhoeic dermatitis of the scalp.

#### **4.2 Posology and method of administration**

*Adults, including elderly patients and Children :* A few drops of Elocon Scalp Lotion should be applied to affected scalp sites, once daily; massage gently and thoroughly until the medication disappears.

Use of topical corticosteroids in children should be limited to the least amount compatible with an effective therapeutic regimen and duration of treatment should be no more than 5 days.

### **4.3 Contraindications**

Elocon Scalp Lotion is contraindicated in skin atrophy, bacterial (e.g. impetigo, pyoderma), 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 scalp. Elocon should not be used on wounds or on skin which is ulcerated. Elocon Scalp 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If irritation or sensitisation develop with the use of Elocon, treatment should be withdrawn and appropriate therapy instituted.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 corticosteroids 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 Elocon 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. 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 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 Scalp Lotion contains propylene glycol which may cause skin irritation.

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

#### **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 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. 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 Elocon 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, Elocon 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. Elocon 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

<b>Table 1:</b> Treatment-related adverse reactions reported with Elocon by body system and frequency  Very common ( $\geq 1/10$ ); common ( $\geq 1/100$ , $< 1/10$ ); uncommon ( $\geq 1/1,000$ , $< 1/100$ ); rare ( $\geq 1/10,000$ , $< 1/1,000$ ); very rare ( $< 1/10,000$ ); not known (cannot be estimated from available data)	
<b>Infections and infestations</b>  Not known   Very rare   <b>Nervous system disorders</b>  Not known   Very rare   <b>Skin and subcutaneous tissue disorders</b>  Not known      Very rare   <b>General disorders and administration site conditions</b>  Not known	Infection, furuncle   Folliculitis   Paraesthesia,  Burning sensation   Dermatitis contact, skin hypopigmentation, hypertrichosis, skin striae, dermatitis acneiform, skin atrophy   Pruritus   Application site pain, application site reactions

<b>Eye disorders</b> Not known	Vision blurred (see also section 4.4)
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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. Healthcare professionals are asked to report any suspected adverse reactions via ADR Reporting, Website:  
[www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal).

## **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 phosphate monobasic dihydrate;  
phosphoric acid;  
purified water.

## **6.2 Incompatibilities**

None known.

## **6.3 Shelf life**

36 months

## **6.4 Special precautions for storage**

Store below 25°C.

**6.5 Nature and contents of container**

30ml white LDPE bottles with LDPE dropper and white Polypropylene cap.

**6.6 Special precautions for disposal and other handling**

Not applicable

**7 MARKETING AUTHORISATION HOLDER**

Merck Sharp & Dohme Limited  
Hertford Road  
Hoddesdon  
Hertfordshire  
EN11 9BU  
UK

**8 MARKETING AUTHORISATION NUMBER(S)**

MA058/02301

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

15<sup>th</sup> September 2006/ 02<sup>nd</sup> October 2012

**10 DATE OF REVISION OF THE TEXT**

August 2018

**11 LEGAL CATEGORY**

Prescription Only Medicine