NEW ZEALAND DATA SHEET

1 PRODUCT NAME

ELOCON

Elocon Alcohol Free Topical cream, 0.1% w/w
Elocon Topical ointment, 0.1% w/w
Elocon Lotion, 0.1% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains mometasone furoate 1mg (0.1 w/w).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Elocon Topical Ointment is a white to off white ointment.

Elocon Topical Alcohol Free Cream is a white to off white cream.

Elocon Lotion is a colourless to light yellow lotion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Elocon Alcohol Free Cream, Elocon Ointment and Lotion are indicated for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, such as psoriasis and atopic dermatitis.

Elocon Lotion is also suitable for scalp psoriasis and seborrhoeic dermatitis.

4.2 Dose and method of administration

A thin film of Elocon Alcohol Free Cream or Elocon Ointment should be applied to the affected skin areas once daily. Elocon Alcohol Free Cream is suitable for moist lesions; the ointment should be used for dry, scaling and fissured lesions.

Apply a few drops of Elocon Lotion to affected skin areas including scalp sites once daily; massage gently and thoroughly until the medication disappears

4.3 Contraindications

Elocon Alcohol Free Cream, Elocon Ointment and Lotion are contraindicated in patients who are hypersensitive to mometasone furoate or to other corticosteroids. Like other topical corticosteroids, Elocon Alcohol Free and Elocon is contraindicated in most viral infections of

the skin, tuberculosis, acne rosacea, perioral dermatitis, fungal skin infections and ulcerative conditions.

4.4 Special warnings and precautions for use

If irritation or sensitisation develops with the use of Elocon Alcohol Free Cream, Elocon Ointment or Lotion treatment should be discontinued and appropriate therapy instituted.

In the presence of an infection, use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, Elocon Alcohol Free and Elocon should be discontinued until the infection is controlled adequately.

Babies and children up to four years should not be treated with topical steroids for longer than three weeks. In infants the napkin may act as an occlusive dressing and increase absorption. Adrenal suppression is more likely to occur in infants and children.

Any of the side effects that have been reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long term use is anticipated, particularly in infants and children. Paediatric patients may demonstrate greater susceptibility to topical corticosteroid induced HPA axis suppression and Cushing's syndrome than adults because of a larger skin surface area to body weight ratio. Use of topical corticosteroids in children should be limited to the least amount required for a therapeutic effect. Chronic corticosteroid therapy may interfere with growth and development of 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.

Elocon Alcohol Free Cream, Elocon Ointment or Lotion should not be used on or around the eyes. The use of topical corticosteroids on the face can exacerbate rosacea and lead to peri-orofacial dermatitis. Patients should be warned against using Elocon Alcohol Free and Elocon on the face except on medical advice and any use on the face should be restricted to short periods.

Prolonged use on flexures and intertriginous areas is undesirable.

4.5 Interaction with other medicines and other forms of interaction

None know.

4.6 Fertility, pregnancy and lactation

Pregnancy
Safe use of Elocon Alcohol Free Cream, Elocon Ointment and Lotion in pregnant women has not been established. Topical corticosteroids should be used during pregnancy only if

the potential benefit justifies the potential risk to the foetus. Drugs of this class should not be used on pregnant patients in large amounts or for prolonged periods of time.

Breast-feeding
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, a decision should be made whether breastfeeding should be discontinued or Elocon Alcohol Free Cream, Elocon Ointment or Lotion be discontinued, taking into account the importance of the drug to the mother.

Topical corticosteroids should not be applied to the breasts prior to nursing.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Elocon Alcohol Free Cream, Elocon Ointment and Lotion are generally well tolerated. Pruritis, burning, tingling, stinging, signs of skin atrophy, folliculitis and acneiform reaction have been reported in less than 5% of patients.

Other local adverse reactions reported in less than 1% of patients include erythema, furunculosis, dermatitis, abscess, aggravated allergy, increased lesion size, disease exacerbation, paraesthesia, dry skin, pimples and papular and pustular formation.

Systemic adverse reactions, such as vision blurred, have also been reported with the use of topical corticosteroids.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

Excessive, prolonged use of topical corticosteroids can suppress pituitary adrenal function resulting in secondary adrenal insufficiency. Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764 766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mometasone, ATC code: D07AC13

Mometasone furoate is a synthetic corticosteroid, exhibiting anti-inflammatory, antipruritic and vasoconstrictive properties.

In laboratory animals, mometasone furoate exhibits potent topical anti-inflammatory activity but approximately half of the suppressive effect on the HPA (hypothalamic pituitary adrenal) axis when compared with equivalent doses of betamethasone valerate. The topical to systemic potency ratio of mometasone furoate is approximately 3 to 10 times that of betamethasone valerate in animal studies.

The local irritation and sensitisation potentials of mometasone furoate cream and ointment were evaluated in rabbits and guinea pigs. Following topical application in rabbits, the dermal response to mometasone furoate cream was characterised by very slight erythema, occasional appearance of papules, atonia, desquamation and wrinkling. Mometasone furoate was not a sensitiser in guinea pigs.

5.2 Pharmacokinetic properties

Following topical application of radio-labelled mometasone furoate in animals, systemic absorption was minimal in all species studied, ranging from approximately 2% in dogs to 6% in rabbits over a 5 to 7 day period.

The percutaneous absorption of Elocon was evaluated in healthy volunteers receiving a single application of radio labelled mometasone furoate cream 0.1% which remained on intact skin for eight hours. Based on the radioactivity excreted in the urine and faeces during the five day study period, approximately 0.4% of the applied dose was absorbed systemically. In a similar study conducted using the ointment formulation, approximately 0.7% of the applied dose was absorbed systemically.

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 Data Sheet.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Elocon Alcohol Free Cream
Aluminium starch octenylsuccinate
Hexylene glycol
Phosphatidylcholines, soya, hydrogenated
Phosphoric acid
Purified water
Titanium dioxide
White beeswax
White soft paraffin

Elocon Ointment
Hexylene glycol
Phosphoric acid
Propylene glycol monostearate
Purified water
White beeswax

White soft paraffin

Elocon Lotion
Hyprolose
Isopropyl alcohol
Monobasic sodium phosphate monohydrate
Phosphoric acid
Propylene glycol
Water

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

Elocon Alcohol Free Cream, Elocon Lotion
24 months

Elocon Ointment
36 months

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

Elocon Ointment: *5g, 15g, *45g and 50g tubes
Elocon Alcohol Free Cream: *5g, 15g, *45g and 50g tubes
Elocon Lotion: 30mL, *50mL, and *100mL bottles

*Not currently supplied

6.6 Special precautions for disposal

Not applicable.

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

Organon New Zealand Limited
123 Carlton Gore Road
Newmarket
Auckland
Tel: 0800 111 700

9 DATE OF FIRST APPROVAL

17 October 1991

10 DATE OF REVISION OF THE TEXT

1 December 2020

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SUMMARY TABLE OF CHANGES

Date Changed	Summary of Changes
01-Dec-2020	Section 8: Amend sponsor details due to transfer of sponsorship