SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

ELOCON® CREAM

ELOCON® OINTMENT

ELOCON® LOTION

COMPOSITION

Each gram of ELOCON Cream contains 1 mg mometasone furoate (micronised) in a cream base of hexylene glycol, hydrogenated soybean lecithin, phosphoric acid, titanium dioxide, starch octenylsuccinate, white wax, white soft paraffin and purified water.

Each gram of ELOCON Ointment contains 1 mg mometasone furoate (micronised) in a base containing hexylene glycol, phosphoric acid, propylene glycol stearate, white beeswax, white soft paraffin and purified water.

Each gram of ELOCON Lotion contains 1 mg mometasone furoate (micronised) in a liquid containing hydroxypropylcellulose, isopropyl alcohol, monobasic sodium phosphate, phosphoric acid, propylene glycol and purified water.

PHARMACOLOGICAL CLASSIFICATION

A.13.4.1 Corticosteroids with or without anti-infective agents

PHARMACOLOGICAL ACTION

ELOCON has anti-inflammatory, antipruritic and vasoconstrictive actions. ELOCON falls within the medium range of potency.

INDICATIONS

ELOCON is indicated for the relief of the inflammatory manifestations of psoriasis and corticosteroid-responsive dermatoses. ELOCON Lotion may be applied to scalp lesions.

CONTRAINDICATIONS

ELOCON is contraindicated in those patients with a history of sensitivity reactions to any of its components.

ELOCON is contraindicated in the treatment of herpes simplex, vaccinia or varicella.

WARNING AND SPECIAL PRECAUTIONS

ELOCON is **not** for ophthalmic use.

If irritation or sensitisation develops with the use of ELOCON, treatment should be discontinued and appropriate therapy instituted.

Systemic absorption of ELOCON may occur, particularly under the following conditions:

- when large quantities are used
- when application is made to wide areas of the body, to damaged skin and
- when the occlusive dressing technique is applied.

Depression of the hypothalamic-pituitary-adrenal axis with consequent suppression of the adrenal gland may occur. These effects are most likely to be severe in children. Growth may be retarded and a Cushingoid state may be produced. Benign intracranial hypertension has been rarely reported.

Evidence of HPA axis suppression may be evaluated by periodic determinations of ACTH stimulation, AM plasma cortisol and urinary free cortisol tests.

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.

Long-term continuous treatment with ELOCON should be avoided as far as possible as this may cause atrophic changes in the skin leading to thinning, loss of elasticity, dilatation of superficial blood vessels, telangiectasiae and ecchymoses. These changes are particularly likely to occur on the face and when occlusive dressings are used.

If a secondary microbial skin infection is present suitable concomitant antimicrobial therapy should be instituted.

ELOCON should be used with particular caution in facial dermatoses, and only for short periods. A steroid rosacea-like facies may be produced.

ELOCON should be used with caution near the eyes.

ELOCON should be used for short courses only. Safety for use longer than 3 weeks has not been established. Regular review should be made of the necessity for continuing therapy.

ELOCON should not be used in the nappy areas in infants for flexural eruptions and ideally it should not be applied to infants and young children (under 2 years) at all.

Since safety and efficacy of ELOCON Cream and Ointment have not been established in paediatric patients below 2 years of age, its use in this age group is not recommended.

The treatment of psoriasis with ELOCON may provoke the pustular form of the disease.

ELOCON should not be applied to any skin crease areas.

PREGNANCY AND LACTATION

Corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore ELOCON should not be used during pregnancy.

The use of ELOCON is not recommended for mothers who are breastfeeding.

DOSAGE AND DIRECTIONS FOR USE

A thin film of ELOCON Cream or Ointment should be applied to completely cover the affected area once daily.

ELOCON Cream and Ointment may be used with caution in paediatric patients 2 years of age or older. Safety and efficacy of ELOCON Cream and Ointment in paediatric patients for more than 3 weeks of use have not been established. Use in paediatric patients under 2 years of age is not recommended.

A few drops of ELOCON Lotion should be applied to the affected skin area and massaged gently and thoroughly into the skin once daily.

Treatment should be discontinued when the dermatologic disorder is controlled. According to clinical response, duration of therapy may vary from a few days to a longer period of time. However, treatment should not be continued for more than 3 weeks without patient re-evaluation.

SIDE EFFECTS

Adverse reactions that have been reported with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria and blurred vision.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See **WARNINGS AND SPECIAL PRECAUTIONS and SIDE EFFECTS**.

Symptoms: Excessive or prolonged use of ELOCON can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency, but may also produce manifestations of hypercorticism, including Cushing syndrome.

Treatment: Treatment is symptomatic and supportive. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

IDENTIFICATION

ELOCON Cream: A smooth, white to off-white cream.

ELOCON Ointment: A smooth, white to off-white, opaque ointment.

ELOCON Lotion: A colourless to light yellow, smooth lotion.

PRESENTATION

ELOCON Cream: Tubes of 20 g

ELOCON Ointment: Tubes of 20 g

ELOCON Lotion: White, plastic bottles of 30 ml

STORAGE INSTRUCTIONS

Elocon Cream and Ointment: Store at or below 25 °C. Protect from light.

Elocon Lotion: Store at or below 30 °C. Protect from light.

Keep out of reach of children.

REGISTRATION NUMBERS

ELOCON Cream: V/13.4.1/272

ELOCON Ointment: V/13.4.1/273

ELOCON Lotion: X/13.4.1/266

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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DATE OF PUBLICATION

Date of Registration:

Elocon Cream: 02 August 1989

Elocon Ointment: 02 August 1989

Elocon Lotion: 19 September 1991

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