

Mometasone

Core Safety Profile

Elocon (mometasone furoate) Cream, Ointment, and Lotion Formulations

4.3 Contraindications

Elocon is contraindicated in facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritus, napkin eruptions, bacterial (e.g. impetigo, pyoderma), viral (e.g. herpes simplex, herpes zoster, chickenpox, verrucae vulgares, condylomata acuminata, molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections, varicella, tuberculosis, syphilis or post-vaccine reactions. Elocon should not be used on wounds or on skin which is ulcerated. Elocon should not be used in patients who are sensitive to mometasone furoate, to other corticosteroids, or to any ingredient in these preparations.

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If irritation or sensitisation develop with the use of Elocon, treatment should be withdrawn and appropriate therapy instituted.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 favorable 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.

Paediatric 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, Elocon is not recommended in this age group.

Local and systemic toxicity is common especially following long continued use on large areas of damaged skin, in flexures and with polythene occlusion. If used in childhood, or on the face, occlusion should not be used. If used on the face, courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age.

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.

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 should not be applied to the eyelids because of the potential risk of glaucoma simplex or subcapsular cataract.

Elocon Cream and Lotion contain propylene glycol which may cause skin irritation.

Elocon Cream contains stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

Elocon Ointment contains propylene glycol which may cause skin irritation.

Elocon topical preparations are not for ophthalmic use.

4.5 Interaction with other medicinal products and other forms of interaction (see also section 4.4)

None stated.

4.6 Pregnancy and lactation

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. 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. 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 fetus.

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 stated.

4.8 Undesirable effects

Table 1: 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 the available data)	
Infections and infestations Not known Very rare Nervous system disorders Not known Very rare Skin and subcutaneous tissue disorders Not known	Infection, furuncle Folliculitis Paraesthesia, Burning sensation Dermatitis contact, perioral dermatitis, skin hypopigmentation, hypertrichosis, skin striae,

Very rare	maceration, miliaria, dermatitis acneiform, skin atrophy
General disorders and administration site conditions	Pruritus
Not known	Application site pain, application site reactions

Local adverse reactions reported infrequently with topical dermatologic corticosteroids include: dry skin, skin irritation, dermatitis, skin maceration, heat rash, 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.

4.9 Overdose

Excessive, prolonged use of topical corticosteroids can suppress hypothalamic-pituitary-adrenal function resulting in secondary adrenal insufficiency which is usually reversible.

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.