HOE
Est. 1979

ELOSONE

DESCRIPTION: *Elosone Cream 0.1% w/w* - A white cream containing Mometasone Furoate 0.1% w/w with Methyl Paraben 0.08% w/w and Propyl Paraben 0.02% w/w as preservative.
Elosone Ointment 0.1% w/w - A white ointment containing Mometasone Furoate 0.1% w/w.
Elosone Lotion 0.1% w/v - A slightly viscous solution containing Mometasone Furoate 0.1% w/v with Methyl Paraben 0.1% w/v as preservative.

PHARMACODYNAMICS: Mometasone Furoate, a synthetic corticosteroid, exhibits anti-inflammatory, antipruritic and vasoconstrictive properties. Corticosteroids diffuse across cell membranes and bind with specific cytoplasmic receptors. These complexes then enter the cell nucleus, bind to DNA (chromatin), and stimulate transcription of messenger RNA (mRNA) and subsequent protein synthesis of various inhibitory enzymes responsible for the anti-inflammatory effects of topical corticosteroid.

PHARMACOKINETICS: Corticosteroids are extensively bound to plasma protein. Only unbound corticosteroids have pharmacological effects or are metabolized.They are metabolized mainly in the liver and also in the kidneys, and are excreted in the urine.When applied topically, particularly to large areas,when the skin is broken or under occlusive dressings, corticosteroids may be absorbed in sufficient amounts to produce systemic effects.

INDICATIONS: *Elosone Cream & Ointment 0.1% w/w* - Indicated for the relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses. *Elosone Lotion 0.1% w/v* - Indicated for the relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses, which includes scalp lesions.

CONTRAINDICATIONS: Elosone is contraindicated in patients who are sensitive to Mometasone Furoate or to other corticosteroids or to any component of these preparations. Risk vs. benefit should be considered when the following medical problems exist: allergy to corticosteroids, infection at treatment site, skin atrophy, cataracts, diabetes mellitus, glaucoma and tuberculosis.

DRUG INTERACTIONS: Unknown.

ADVERSE EFFECTS: Local adverse reactions reported very rarely with Elosone Cream 0.1% w/w include paresthesia, pruritus and signs of skin atrophy. Local adverse reactions rarely reported with Elosone Ointment 0.1% w/w include burning, pruritus, tingling/stinging and signs of skin atrophy. Local adverse reactions reported very rarely with Elosone Lotion 0.1% w/v include burning, folliculitis, acneiform reaction, pruritus and signs of skin atrophy.
The following local adverse reactions have been reported infrequently with the use of other topical corticosteroids: irritation, hypertrichosis, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

PRECAUTIONS/WARNINGS: If irritation or sensitization develops with the use of Elosone, treatment should be discontinued and appropriate therapy instituted. In the presense of an infection, 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 controlled adequately.
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 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 hypothalamic-pituitary-adrenal axis suppression and Cushing's Syndrome than mature patients because of a larger skin surface area to body weight ratio. Use of topical corticosteroid in children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with growth and development of children. Elosone is not for ophthalmic use.

PREGNANCY AND LACTATION: Topical corticosteroids should not be extensively in large amounts or for protracted period in pregnant patients or patients who are planning to become pregnant. Adequate and well-controlled studies in humans have not been done. Studies in animals have shown that topical corticosteroids are systematically absorbed and may cause fetal abnormalities, especially when used in large amounts, with occlusive dressings, for prolonged period of time, or if the more potent agents are used.
It is not known whether topical corticosteroids are distributed into breast milk. However, problems in humans have not been documented. Systemic corticosteroids are distributed into breast milk and may cause unwanted effects, such as growth suppression, in the infant. Topical corticosteroids should not be applied to the breasts prior to nursing.

ROUTE OF ADMINISTRATION : Topical.

RECOMMENDED DOSAGE: *Elosone Cream & Ointment 0.1% w/w* - A thin film should be applied to the affected skin areas once daily until lesion heals or for duration of three weeks, whichever is sooner as directed by your doctor or pharmacist.
Elosone Lotion 0.1% w/v - Apply a few drops to affected skin areas including scalp sites once daily; massage gently and thoroughly until the medication disappears.

SYMPTOMS AND TREATMENT FOR OVERDOSE AND ANTIDOTE(S): Corticosteroid applied to the skin can be absorbed in sufficient amounts to produce systemic effects such as hypothalamic-pituitary-adrenal axis suppression, manifestation of Cushing's Syndrome, hyperglycaemia and glycosuria. Tests which may be helpful in evaluating hypothalamic-pituitary-adrenal axis suppression include urinary free cortisol test and ACTH stimulation test. If hypothalamic-pituitary-adrenal axis suppression is found, then the drug should be withdrawn, frequency of application reduced or a weaker steroid used. Supplemental systemic corticosteroid may be required if signs and symptoms of steroid withdrawal occurs.

PACKING: *Elosone Cream & Ointment 0.1% w/w* - Collapsible aluminium tube of 5g and 15g. 45g is for export only.
Elosone Lotion 0.1% w/v - 30ml plastic bottle.

STORAGE: Keep container well closed. Protect from light. Store below 30ºC. For external use only. Keep out of reach of children.
Recommended shelf-life:3 years.
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Manufactured by:

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