

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Product Name

Elosone Cream 0.1% w/w

1.2 Strength

Mometasone Furoate

1.3 Pharmaceutical Dosage Form

A white cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 1mg Mometasone Furoate

3. PHARMACEUTICAL FORM

Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

4.2 Posology and method of administration

A thin film should be applied to the affected skin areas once daily until the lesion heals or for duration of three weeks, whichever is sooner as directed by your doctor or pharmacist.

4.3 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.

4.4 Special warnings and special precautions for use

If irritation or sensitization develops with the use of Elosone, 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, 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 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 hypothalamic-pituitary axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio. Use of topical corticosteroids 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.

4.5 Interaction with other FPPs and other forms of interaction

Unknown.

4.6 Pregnancy and lactation

Topical corticosteroids should not be used extensively in large amounts or for protracted periods in pregnant patients or in 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 systemically absorbed and may cause fetal abnormalities, especially when used in large amount, 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.

4.7 Effects on ability to drive and use machines

Unknown.

4.8 Undesirable effects

Local adverse reactions reported very rarely with Elosone Cream 0.1% w/w include paresthesia, 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, and allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliria.

4.9 Overdose

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 evaluation hypothalamic-pituitary-adrenal axis suppression include urinary free cortisol test and ACTH stimulation test. If the hypothalamic-pituitary-adrenal axis suppression is found, then the drug should be withdrawn, frequency of application reduced or a weaker steroid used. Supplemental systemic corticosteroids may be required if signs and symptoms of steroid withdrawal occurs.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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 corticosteroids.

5.2 Pharmacokinetic properties

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 kidney, 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.

5.3 Preclinical safety data

Unknown

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Metylparaben, Propylparaben, White Soft Paraffin, Liquid Paraffin, Cetostearyl Alcohol, Macrogol Cetostearyl Ether, Propylene Glycol, Phosphoric Acid 85%, Sodium Dihydrogen Phosphate Dihydrate and Purified Water.

6.2 Incompatibilities

Unknown

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Collapsible aluminium tube

6.6 Instructions for use and handling

No special requirement

7. MARKETING AUTHORISATION HOLDER

HOE Pharmaceuticals Sdn. Bhd.

Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor, MALAYSIA.

8. MARKETING AUTHORISATION NUMBERS

05323/07250/REN/2020

07773/07938/VAR/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation : 17/10/2010

Renewal of authorisation : 07/09/2025

10. DATE OF REVISION OF THE TEXT

04th January 2024