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 0.1% w/w

1.3 Pharmaceutical Dosage Form
Cream

Prescription only medicines (POM)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Qualitative
Mometasone Furoate 0.1% w/w

2.2 Quantitative
1g cream contains 1mg of Mometasone Furoate

3. PHARMACEUTICAL FORM

A white cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Indicated for the relief of inflammatory and pruritic manifestations of psoriasis (excluding widespread plague psoriasis) and atopic dermatitis.

4.2 Posology and method of administration

Adults, including elderly patients and children: A thin film of Elosone Cream should be applied to the affected areas of skin once daily.

Use of topical corticosteroids in children or on the face should be limited to the least amount compatible with an effective therapeutic regimen and duration of treatment should be no more than 5 days.

4.3 Contraindications

This product is contraindicated in facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritis, napkin eruptions, bacterial (e.g. impetigo, pyodermas), viral (e.g. herpes simplex, herpes zoster and chickenpox verrucae vulgares, condylomata acuminate, molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections, varicella, tuberculosis, syphilis or post-vaccine reactions.

Elosone should not be used on wounds or on skin which is ulcerated. Elosone should not be used in patients who are sensitive to mometasone furoate or to other corticosteroids or to any of the excipients listed in Section 6.1.

4.4 Special warnings and special precautions for use

If irritation or sensitization develops with the use of Elosone, treatment should be withdrawn and appropriate therapy instituted.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 favourable 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.

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.

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 Elosone in paediatric patients below 2 years of age have not been established, its use in this age group is not recommended.

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 and occlusion should not be used. Long term continuous therapy should be avoided in all patients irrespective of age.

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,

Elosone topical preparations are not for ophthalmic use, including the eyelids, because of the very rare risk of glaucoma simplex or subcapsular cataract.

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.

Instruct patients not to smoke or go near naked flames-risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other FPPs and other forms of interaction.
Unknown.

4.6 Pregnancy and lactation

Pregnancy
During pregnancy treatment with Elosone 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 Elosone 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. There may therefore be a very small risk of such effects in the human foetus. Like other topically applied glucocorticoids, Elosone should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or the foetus.

Lactation
It is not known whether topical administration of corticosteroids could result insufficient systemic absorption to produce detectable quantities in breast milk. Elosone 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
Unknown

4.8 Undesirable effects

Local adverse reaction reported infrequently with topical dermatologic corticosteroids include: skin dryness, irritation, dermatitis, perioral dermatitis, maceration of the skin, miliaria 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 to have little or no toxic effect in the unlikely event of accidental oral ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mometasone Furoate exhibit marked anti-inflammatory activity and marked anti-psoriatic activity in standard animal predictive models. In the croton oil assay in mice, mometasone was equipotent to betamethasone valerate after single application and about 8 times as potent after five applications. In guinea pigs, mometasone was approximately twice as potent as betamethasone valerate in reducing m.ovalis -induced epidermal acanthosis (i.e. anti-psoriatic activity) after 14 applications.

5.2 Pharmacokinetic properties

The studies have indicated that systemic absorption following topical application of mometasone furoate cream 0.1% is minimal, approximately 0.4% of the applied dose in man, the majority of which is excreted within 72 hours following application. Characterisation of metabolites was not feasible owing to the small amounts present in plasma and excreta.

5.3 Preclinical safety

data Unknown

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methylparaben, 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

Three (3) years

6.4 Special precautions for storage

Store below 30°C. Keep out of reach of children.

6.5 Nature and contents of container
15g in aluminum tube

6.6 Instructions for use and handling No special requirement

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

HOE Pharmaceuticals Sdn. Bhd.,
Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor Darul Ehsan, MALAYSIA.

8. MARKETING AUTHORISATION NUMBERS
TAN 21 HM 0126

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
29/03/2020

10. DATE OF REVISION OF THE TEXT
March 2021