SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICALS PRODUCT

Elosone Lotion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml solution containing 1 mg of Mometasone Furoate

3. PHARMACEUTICAL FORM

A slightly viscous solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses, which includes scalp lesions.

4.2 Posology and method of administration

Apply a few drops to affected skin areas including scalp sites once daily; massage gently and thoroughly until the medication disappears.

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 exists: allergy to corticosteroids, infection at treatment site, skin atrophy, cataracts, diabetes mellitus, glaucoma and tuberculosis.

4.4 Special warning and 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 medicinal products and other forms of interactions

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 systematically 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 machine

Unknown.

4.8 Undesirable effects

Local adverse reactions reported very rarely with Elosone Lotion 0.1% w/v including 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, hyperpigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

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 glucosuria. 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 Fuorate, 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

Not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phosphoric Acid, Methylparaben, Hydroxypropyl Methylcellulose, Isopropyl Alcohol and Purified Water.

6.2 Incompatibilities

None.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30ºC.

6.5 Nature and contents of container

30ml PE bottle

7. MARKETING AUTHORIZATION HOLDER

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

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

   05549/07617/REN/2020
   06735/07646/VAR/2021

9. DATE OF FIRST AUTHORIZATION/ RENEWAL OF THE AUTHORIZATION

   Date of first authorization: 29/03/2017

   Date of last renewal: Dec 11, 2020

10. DATE OF REVISION OF THE TEXT
    22nd June 2020