SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Haelan Ointment
Fludroxycortide 0.0125% w/w Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Fludroxycortide 0.0125% w/w.

Excipient with known effect
Cetyl alcohol
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment for topical administration.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Adults and children: Eczema and dermatitis of all types including childhood and adult atopic eczema, photodermatitis, primary irritant and allergic dermatitis, lichen planus, lichen simplex, prurigo nodularis, discoid lupus erythematosus, necrobiosis lipoidica, pretibial myxoedema and erthroderma.

4.2. Posology and method of administration

Posology
For dry, scaly lesions, the ointment should be applied as a thin film to the affected area two or three times daily.

Method of administration
The elderly: As the skin is likely to be thin, apply sparingly to avoid development of atrophy.

Dilution is not recommended, but if considered necessary, white soft paraffin BP may be used.

4.3. Contraindications

Tuberculosis of the skin, facial rosacea, acne vulgaris, perioral dermatitis, perianal and genital pruritus, dermatoses in infancy including eczema, dermatitic napkin eruption, bacterial (impetigo), viral (herpes simplex) and fungal (candida or dermatophyte) infections.

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4. Special warnings and precautions for use

Preparations of Haelan are not intended for ophthalmic use.

Local and systemic toxicity is common especially following long-term continuous use, continued use on large areas of damaged skin, flexures and with polythene occlusion.

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression (see section 4.8). Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using urinary-free cortisol and ACTH stimulation tests. 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. Recovery of HPA axis function is generally prompt and complete on discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, so that supplemental systemic corticosteroids are required.

Long-term continuous therapy should be avoided in all patients irrespective of age.

Application under occlusion should be restricted to dermatoses in very limited areas.

If used on the face, courses should be limited to five days and occlusion should not be used.

In the presence of skin infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, Fludroxycortide should be discontinued until the infection has been adequately controlled.

Cetyl alcohol may cause local skin reactions (e.g. contact dermatitis).

Healthcare professionals should be aware that if this product comes into contact with dressings, clothing and bedding, the fabric can be easily ignited with a naked flame. Patients should be warned of this risk and advised to keep away from fire when using this product.

<u>Paediatric population</u>
Usage in children: If used in children, courses should be limited to five days and occlusion should not be used.

Children may absorb proportionally larger amounts of topical corticosteroids and thus may be more susceptible to systemic toxicity. Children may also demonstrate greater susceptibility to topical corticosteroid induced HPA axis

suppression and Cushing's Syndrome than do mature patients because a larger skin surface to body weight ratio. Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

As with all topical steroids, the activity can be enhanced by the use of occlusive dressings. Preparations of Haelan are recommended only as a supplement to, and not as a substitute for, preparations (lotions, wet dressings etc.) used in the conventional management of skin lesions. Haelan ointment does not contain parahydroxybenzoates or lanolin.

4.5. Interaction with other medicinal products and other forms of interaction

Not known

4.6. Fertility, pregnancy and lactation

Pregnancy
There is inadequate evidence of safety in human pregnancy. There may be a very small risk of cleft palate and intra-uterine growth retardation as well as suppression of the neonatal HPA axis. There is evidence of harmful effects in animals.

Use in pregnancy only when there is no safer alternative and when the disease itself carries risks for mother and child.

Breast-feeding
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in the breast milk of nursing mothers. Systemically administered corticosteroids are secreted into the breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to nursing mothers.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

The following local adverse reactions are reported infrequently with topical corticosteroids but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence; burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, miliaria, striae and thinning and dilations of superficial blood vessels producing telangiectasia.

Prolonged use of large doses to extensive areas can result in sufficient systemic absorption to produce generalised manifestations of steroid toxicity and may result in depression of HPA function on discontinuing treatment.

Manifestations of Cushing's Syndrome, hyperglycaemia and glycosuria have occurred in some patients.

Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels and absence of response to ACTH stimulation. Intracranial hypertension including bulging fontanelles, headaches and bilateral papilloedema have also been reported in children receiving topical corticosteroids.

Infected skin lesions, viral, bacterial or fungal may be substantially exacerbated by topical steroid therapy. Wound healing is significantly retarded.

Hypersensitivity reactions may occur.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9. Overdose

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see section 4.4).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, potent (group III), dermatological preparations, ATC code: D07AC07

Fludroxycortide is a fluorinated, synthetic, moderately potent corticosteroid.

As with other topical steroids, the therapeutic effect is primarily the result of its anti-inflammatory, anti-mitotic and anti-synthetic activities.

5.2. Pharmacokinetic properties

Fludroxycortide applied under occlusive dressing has shown therapeutic improvement without disturbance of electrolyte, liver or renal function or suppression of adrenal function.

5.3. Preclinical safety data

There are no preclinical data of relevance to the prescriber in addition to that summarised in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

White soft paraffin
White beeswax
Cetyl alcohol
Sorbitan sequiolate

6.2. Incompatibilities

None known.

6.3. Shelf life

2 years

6.4. Special precautions for storage

Do not store above 25°C

6.5. Nature and contents of container

60g aluminium tubes with screw cap.

6.6. Special precautions for disposal and other handling

No special instructions for disposal and handling.

7. MARKETING AUTHORISATION HOLDER

Typharm Limited
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NR13 6LH

8. MARKETING AUTHORISATION NUMBER

PL 00551/0013

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 February 1999
Date of latest renewal: 26 July 2003

10. DATE OF REVISION OF THE TEXT

12/06/2017