SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Haelan Tape
Fludroxycortide 4 micrograms per square centimetre Tape

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The tape is impregnated with 4 micrograms fludroxycortide per square centimetre.

3. PHARMACEUTICAL FORM

Occlusive tape.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Occlusive topical steroid. Adjunctive therapy for chronic, localised, recalcitrant dermatoses that may respond to topical corticosteroids and particularly dry, scaling lesions.

4.2 Posology and method of administration

Posology

Adults and the Elderly

For application to the skin, which should be clean, dry and shorn of hair. In most instances the tape need only remain in place for 12 out of 24 hours.

Method of administration

Cosmetics may be applied over the tape.

Application: The tape is cut so as to cover the lesion and a quarter inch margin of normal skin. Corners should be rounded off. After removing the lining paper, the tape is applied to the centre of the lesion with gentle pressure and worked to the edges, avoiding excessive tension of the skin. If longer strips of tape are to be applied, the lining paper should be removed progressively.

If irritation or infection develops, remove tape and consult a physician.

Paediatric population

If used in children, courses should be limited to five days and occlusion should not be used (see section 4.4).

4.3 Contraindications

Chicken pox. Vaccinia. Tuberculosis of the skin. Hypersensitivity to any of the components. 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 the surgical tape listed in section 6.1.

4.4 Special warnings and precautions for use

Not advocated for acute and weeping dermatoses.

Local and systemic toxicity of medium and high potency topical corticosteroids 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.

Paediatric population

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 of 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.

4.5 Interaction with other medicinal products and other forms of interaction

None 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 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 dilatations 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, topical corticosteroid. As with other topical steroids, the therapeutic effect is primarily the result of its anti-inflammatory, antimitotic and antisynthetic activities.

5.2 Pharmacokinetic properties

When applied topically, particularly to large areas, when the skin is broken, or under occlusive dressings, corticosteroids may be absorbed in sufficient amounts to cause systemic effects.

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

Blenderm brand surgical tape.

6.2. Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store in a dry place, below 25^{o}C.

6.5 Nature and contents of container

Cardboard dispenser, in a cardboard box, containing 20cm, 50cm or 200cm of translucent, polythene adhesive film, 7.5cm wide, protected by a removable paper liner.

6.6 Special precautions for disposal and other handling

No special instructions for disposal and handling.

7. MARKETING AUTHORISATION HOLDER

Typharm Ltd.
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8. MARKETING AUTHORISATION NUMBER(S)

PL 00551/0014

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 February 1999
Date of latest renewal: 24 August 2001

10 DATE OF REVISION OF THE TEXT

10/06/2016