1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

DOVATE OINTMENT

COMPOSITION

Each 5 g of DOVATE OINTMENT contains 0,0025 g of clobetasol propionate.

Excipients:

Cholesterol, propylene glycol, stearyl alcohol, white beeswax, white soft paraffin.

CATEGORY AND CLASS

A 13.4.1 Dermatological preparation - corticosteroids without anti-infective agents

PHARMACOLOGICAL ACTION

Clobetasol propionate is a highly potent topical corticosteroid.

INDICATIONS

Short term use in the treatment of steroid responsive dermatoses resistant to other less potent topical corticosteroids such as: seborrhoeic dermatitis, atopic dermatitis, lichen chronicus simplex, pruritus ani, psoriasis, later phase of allergic contact dermatitis, later phase of irritant dermatitis, discoid lupus erythematosus and lichen planus.

CONTRAINDICATIONS

DOVATE OINTMENT should not be used in the presence of bacterial (including tuberculous), fungal or viral infections of the skin.

Avoid use in ulcerative skin lesions and in rosacea.

Application to ulcers of the leg.

Long-term use is contraindicated in patients with diabetes mellitus or tuberculosis.

The more potent corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore, DOVATE OINTMENT should not be used during pregnancy (see HUMAN REPRODUCTION).

Known sensitivity to corticosteroids.

WARNINGS AND SPECIAL PRECAUTIONS

FOR EXTERNAL USE ONLY.

DOVATE OINTMENT may under certain circumstances, be absorbed in sufficient amounts to produce systemic effects. Systemic absorption may cause suppression of the pituitary-adrenal axis. Even small amounts absorbed may cause growth retardation in children. As DOVATE OINTMENT contains a highly potent corticosteroid, the risk of absorption is enhanced.

Absorption (and risk of subsequent toxicity) is also enhanced by application for prolonged periods under occlusive dressings, by application to extensive areas or where skin is broken.

Topical application of DOVATE OINTMENT should not be made with occlusive dressing to large areas of the body because of the increased risk if systemic toxicity.

Special care should be exercised in infants and children.

Areas of body most likely to suffer local damage are the face and eyelids; the intertriginous areas, the neck, axillae, etc. are more permeable.

Long-term topical use is best avoided, especially in children.

Children may absorb proportionally larger amounts of DOVATE OINTMENT because of a larger skin surface area to body-mass ratio, and thus be more susceptible to systemic toxicity.

Tight-fitting nappies or plastic pants should not be used on an infant being treated in the nappy area, as these garments may constitute occlusive dressings.

Use with care in porphyrics.

Effects on ability to drive and use machines

Not known.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

The safety of DOVATE OINTMENT in pregnancy and lactation has not been established (see

CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

Apply once or twice daily sparingly to the affected area until improvement occurs. Therapy should be discontinued when control is achieved. In the more responsive conditions this may be within a few days. If a longer course is necessary, it is recommended that treatment should not be continued for longer than four weeks without the patient's condition being reviewed.

Repeated short courses of DOVATE OINTMENT may be used to control exacerbations. If continuous steroid treatment is necessary, a less potent preparation should be used.

In very resistant lesions, especially where there is hyperkeratosis, the treatment area must be occluded for part of each 24 hours. Thereafter improvement can usually be maintained by application without occlusion.

SIDE EFFECTS

Even small amounts absorbed may cause growth retardation in children.

Once absorbed through the skin the pharmacokinetic pathway is similar to systemically administered corticosteroids. Depression of the hypothalamic-pituitary-adrenal-axis with consequent suppression of the adrenal gland may occur.

Application of DOVATE OINTMENT to the skin has led to loss of skin collagen and subcutaneous atrophy; local hypopigmentation of deeply pigmented skin has been reported.

In the treatment of severe psoriasis DOVATE OINTMENT may induce generalised pustular psoriasis during therapy or on withdrawal.

Other local effects include atrophy of the epidermis and dermal collagen (causing atrophic striae), drying of the skin and telangiectasiae.

Increased fragility of cutaneous vessels may result in bruising and purpura.

Rosacea-like dermatitis, perioral dermatitis and acneiform eruptions may occur.

Occlusive dressings are associated with maceration of the skin and miliaria.

Local infection may be worsened and spread enhanced.

The topical application of DOVATE OINTMENT to the eyes has produced corneal ulcers, raised intra-ocular pressure, and reduced visual function.

Depression of the hypothalamic-pituitary-adrenal-axis in children may retard growth and development.

Benign intracranial hypertension has been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See SIDE EFFECTS.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

A soft, smooth off-white ointment.

PRESENTATION

25 g ointment are packed into an aluminium, collapsible tube, externally printed and internally plain, close nozzle fitted with a white self-piercing, high density polyethylene cap, and placed in a unit cardboard carton together with a leaflet.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Keep tube tightly closed.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

27/13.4.1/0122

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

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