

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Alphaderm 1% & 10%w/w Cream

2. Qualitative And Quantitative Composition

Alphaderm cream contains the active ingredients Hydrocortisone, PhEur 1% w/w and Urea, BP 10% w/w.

3. Pharmaceutical Form

Translucent white cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of all dry ichthyotic, eczematous conditions of the skin, including atopic, infantile, chronic allergic and irritant eczema, asteatotic, hyperkeratotic and lichenified eczema, neurodermatitis and prurigo.

4.2 Posology and method of administration

Adults, children and the elderly. A small amount should be applied topically to the preferably dry affected areas twice daily. In resistant lesions occlusive dressings may be used but this is usually unnecessary because of the self occlusive nature of the special base.

4.3 Contraindications

Primary bacterial, viral and fungal diseases of the skin and secondarily infected eczemas or intertrigo acne, perioral dermatitis, rosacea and, in general, should not be used on weeping surfaces.

Known hypersensitivity to the active ingredients or any of its excipients.

4.4 Special warnings and special precautions for use

Caution should be exercised when using in children. In infants and children, long term continuous therapy should be avoided, as adrenal suppression can occur even without occlusion. Excessive absorption may occur when applied under napkins. Where possible treatment in infants should be limited to 5-7 days.

Application to moist or fissured skin may cause temporary irritation.

As with corticosteroids in general, prolonged application to the face and eyelids is undesirable and the cream should be kept away from the eyes.

4.5 Interaction with other medicinal products and other forms of Interaction

None known.

4.6 Pregnancy and lactation

There is inadequate evidence for 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 may, therefore, be a very small risk of such effects in the human foetus.

4.7 Effects on ability to drive and use machines

Alphaderm does not interfere with the ability to drive or use machines.

4.8 Undesirable effects

If used correctly Alphaderm is unlikely to cause side effects. However, the following events have been observed with topical steroids, and although are rare with hydrocortisone, may occur, especially with long-term use; spread and worsening of untreated infection; thinning of the skin; irreversible striae atrophicae and telangiectasia; contact dermatitis, perioral dermatitis; acne; mild depigmentation which may be reversible. Atrophic changes may occur in intertriginous areas or nappy areas in young children.

4.9 Overdose

Chronically, grossly excessive over-use on large areas of skin in, for example, children could result in adrenal suppression of the hypothalamic-pituitary axis (HPA) as well as topical and systemic signs and symptoms of high corticosteroid dosage. In such cases, treatment should not stop abruptly. Adrenal insufficiency may require treatment with systemic hydrocortisone. Ingestion of a large amount of Alphaderm would be expected to result in gastrointestinal irritation, nausea, and possibly vomiting. Symptomatic and supportive care should be given. Liberal oral administration of milk or water may be helpful.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hydrocortisone is a naturally occurring glucocorticoid with proven anti-inflammatory and vasoconstrictive properties. Urea has been demonstrated to have hydrating, keratolytic and anti-pruritic properties. As such, urea has additional therapeutic effect in dry hyperkeratotic skin conditions. Alphaderm cream contains hydrocortisone and urea in a specially formulated base which assists the percutaneous transportation of the active ingredients to the site of action. Due to this formulation, Alphaderm acts as a moderately potent topical corticosteroid. The base is self-occlusive and fulfils the functions of both an ointment and a cream.

5.2 Pharmacokinetic properties

Therapeutic activity of hydrocortisone depends upon the adequate penetration through the horny layer of the skin. The urea in the formulation solubilises part of the hydrocortisone and has a keratolytic effect. Both these factors increase penetration of the hydrocortisone

5.3 Preclinical Safety Data

None stated

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin, maize starch, isopropyl myristate, sycrowax HR-C, palmitic acid, sorbitan laurate and Arlatone G.

6.2 Incompatibilities

None known.

6.3 Shelf life

Two years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Supplied in tubes of 30g and 100g.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

A patient leaflet is provided with details of use and handling of the product.

7. Marketing Authorisation Holder

Alliance Pharmaceuticals Ltd
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8. MARKETING AUTHORISATION NUMBER(S)

PL 16853/0060.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13 February 1990

10. DATE OF REVISION OF THE TEXT

1st February 2010

11. LEGAL STATUS

POM