Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Alphaderm 1% & 10% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains:		
Hydrocortisone	1	% w/w
Urea	10	% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
Translucent, white in appearance.

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 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 Fertility, 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.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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
Glyceryl tribehenate
Palmitic acid
Sorbitan laurate
Polyoxyethylene fatty glyceride

6.2 Incompatibilities

Not applicable.

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

Epoxy lined aluminium tube with membrane seal and white plastic screw cap. Presented in packs of 30 g and 100 g.

Not all pack sizes may be marketed.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Alliance Pharmaceuticals Limited
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8 MARKETING AUTHORISATION NUMBER

PA 943/4/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1978

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

March 2015