SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dioderm 0.1 w/w Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone 0.1% w/w

For excipients see Section 6.1

3. PHARMACEUTICAL FORM

Smooth white aqueous CREAM.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the topical treatment of eczema and dermatitis.

4.2. Posology and Method of Administration

For adults, the elderly and children
Apply to the affected areas twice daily. For infants, the treatment period should not normally exceed 7 days.

4.3 Contra-Indications

As with all topical steroids, Dioderm is not to be used where there is bacterial, viral or
fungal infection.
Not to be used on open wounds, ulcers or broken skin.
Not to be used in cases of sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Although generally regarded as safe, even for long-term administration in adults, there is a potential for overdosage in infancy. Extreme caution is required in dermatoses in infancy, including napkin eruption. In such patients, courses of treatment should not normally exceed 7 days.

Prolonged or extensive uninterrupted application should be avoided, particularly if used on the face or with occlusive dressings.

The excipient propylene glycol may on rare occasions cause skin irritation in sensitive people.

Keep out of the sight and reach of children.

Keep away from the eyes.

For external use only.

Topical steroid withdrawal syndrome
Long term use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advice is recommended in these cases or other treatment options should be considered.

The label will state mild steroid.

Visual disturbance
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5. Interactions with other Medicinal Products and other Forms of Interaction

None known.

4.6. Pregnancy and Lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal 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

None known.

4.8 Undesirable effects

Reported side effects of corticosteroids include skin thinning and striae. Although rare, these could occur even with hydrocortisone, especially when used under occlusion or in the folds of the skin.

Dioderm is usually well tolerated but in the event of a hypersensitivity reaction (allergic contact dermatitis) treatment should be discontinued.

Adverse drug reactions are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1,000 and <1/100), rare (≥1/10,000 and <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reaction
Skin and Subcutaneous Tissue Disorders	Not known	Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)
Eye disorders	Not known	Vision, blurred (see also section 4.4)

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 or search for MHRA Yellow Card in Google Play or Apple App Store.

4.9. Overdose

Under exceptional circumstances, if Dioderm is used excessively, particularly in young children, it is theoretically possible that adrenal suppression and skin thinning may occur. The symptoms are normally reversible on cessation of treatment.

5.1 Pharmacodynamic properties

ATC code: D07AA02 - Pharmacotherapeutic group: Dermatological corticosteroid, weak (group I).

Corticosteroids are used in pharmacological doses for their anti-inflammatory and immunosuppressive glucocorticoid properties which suppress the clinical manifestations of a wide range of diseases. Although many synthetic derivatives have been developed, hydrocortisone is still used widely in topical formulations for inflammatory dermatoses. It has the advantage over its synthetic derivatives that it is metabolised in the skin and therefore cannot accumulate to form a depot which may result in local side effects.

5.2. Pharmacokinetic Properties

The cream formulation of Dioderm was developed in order to optimise the release and partition of its active ingredient, hydrocortisone, into the skin. The hydrocortisone is presented as a saturated or near saturated solution in aqueous propylene glycol, which represents the continuous phase of the emulsion system. It has been shown, by the vasoconstrictor assay on normal skin, that, in this environment, a 0.1% concentration of the hydrocortisone is equivalent to the 1.0% concentration of the official cream formulations appearing in the British Pharmacopoeia where the drug substance is in suspension. Clinical studies have confirmed that 0.1% Dioderm is equivalent to 1.0% Hydrocortisone Cream BP whilst the reduced strength of Dioderm increases the margin of safety.

5.3. Pre-clinical Safety Data

No special information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid

Emulsifying wax

White soft paraffin

Liquid paraffin

Propylene glycol

Purified water

6.2. Incompatibilities

None known.

6.3 Shelf life

24 months in unopened container.

6.4. Special Precautions for Storage

Do not store above 25°C.
Replace cap tightly after use.

6.5. Nature and Content of Container

30 g, 50 g and 100 g membrane sealed epoxy resin coated aluminium collapsible TUBES. High density polyethylene white spiked flowerpot **SCREW CAPS** inverted over the orifice to break the seal. Supplied as original packs (OP).

6.6. Instructions for Use, Handling and Disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Limited
T/A Dermal Laboratories

Tatmore Place, Gosmore
Hitchin
Herts, SG4 7QR
UK

8. MARKETING AUTHORISATION NUMBER

PL 0173/0047

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

16 December 1987 / 24 February 1998

10 DATE OF REVISION OF THE TEXT

06/09/2024