SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dermacort Hydrocortisone Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dermacort Hydrocortisone Cream contains hydrocortisone B.P. 0.1% w/w in a specially formulated, lanolin-free cream base.

3 PHARMACEUTICAL FORM

Cream.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Topical treatment of skin irritations, contact dermatitis, allergic contact dermatitis and rashes due to reactions to plants, insect bite, jewellery, toiletries, deodorants, soaps and detergents. Dermacort is also indicated for the treatment of mild to moderate eczema.

4.2 Posology and method of administration

For cutaneous use.

Method of administration

Adults and children over 10 years:

Apply a thin layer to cover the affected area once or twice a day.

Rub in gently until the cream disappears.

Do not use for more than one week.

4.3 Contraindications

For external use only.

Hypersensitivity to hydrocortisone or to any other excipients listed in section 6.1.

Do not use on the eyes or face, the ano-genital region, on broken or infected skin.

As with all topical steroids, Dermacort is contra-indicated in the presence of viral, bacterial and fungal diseases of the skin.

4.4 Special warnings and precautions for use

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Withdrawal and Misuse

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 advise is recommended in these cases or other treatment options should be considered.

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 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. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation.

Dermacort should not be used during pregnancy.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Eye disorders: Frequency uncommon: Vision, blurred (see also section 4.4).Dermacort is normally well tolerated, but if signs of hypersensitivity appear application should stop immediately.

Skin and Subcutaneous Tissue Disorders: Not known (cannot be estimated from available data) 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)

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 website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercorticism may appear and in this situation topical steroids should be discontinued.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Dermatologicals, ATC code: D07AA02

Corticosteroids are used in pharmacological doses for their anti-inflammatory and immunosuppressive glucocorticoid properties which suppress the clinical manifestation of a wide range of disease. Although many synthetic derivatives have been developed, hydrocortisone is still used widely in topical formulations for mild and transient inflammatory dermatitis. 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 Dermacort 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% concentration where the drug substance is in suspension. Clinical studies have confirmed that 0.1% Dermacort is equivalent to 1.0% hydrocortisone cream BP/BPC whilst the reduced strength of Dermacort increases the margin of safety.

5.3 Preclinical safety data

None applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Emulsifying Ointment
Citric Acid
Purified Water

6.2 Incompatibilities

None applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

Lacquered Aluminium Tubes containing 15g of cream.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Marlborough Pharmaceuticals Ltd
Sovereign House, Miles Gray Road,
Basildon, Essex SS14 3FR, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 23138/0007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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