Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diprosone Lotion 0.05 % (w/w)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone 0.05% w/w as Betamethasone dipropionate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution
A colourless translucent viscous cutaneous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical management of corticosteroid responsive dermatoses.

4.2 Posology and method of administration

Adults and Children :

Apply to the affected area once to twice daily.

4.3 Contraindications

Acne rosacea and perioral dermatitis. Hypersensitivity to any of the ingredients of the lotion contraindicates its use, as does untreated infections of bacterial, viral, tuberculous or fungal origin.

4.4 Special warnings and precautions for use

Do not use on children under 12 years of age without medical supervision. This product should be applied sparingly over a small area once or twice a day for a maximum of one week.

Prolonged use of uninterrupted occlusion (including baby napkins) or use with extensive occlusive dressings may suppress adrenocortical function.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons, including rebound relapses following development of tolerance, risk of generalised pustular psoriasis and local systemic toxicity due to impaired barrier function of the skin. Careful patient supervision is important.

Diprosone is not for ophthalmic use. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result.

General: Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome also can be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Paediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation develops, treatment should be discontinued and appropriate therapy instituted.

There have been a few reports in the literature of the developments of cataracts in patients who have been using corticosteroids for prolonged periods of time. Although it is not possible to rule out systemic corticosteroids as a known factor, prescribers should be aware of the possible role of corticosteroids in cataract development.

Paediatric Use:
Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects than adult patients because of greater absorption due to a larger skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome and intracranial hypertension have been reported in paediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in paediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilloedema.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection has been controlled adequately.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There are no adequate and well controlled studies of the teratogenic potential of topically applied corticosteroids in pregnant women. Therefore topical steroids should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Side effects include local irritation and hypersensitivity.

The following local adverse reactions that have been reported with the use of Diprosone include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

Continuous application without interruption will result in local atrophy of the skin, striae and superficial vascular dilatation, particularly on the face.

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

Excessive prolonged use of topical corticosteroids can suppress hypothalamic pituitary-adrenal functions resulting in secondary adrenal insufficiency which is usually reversible. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, reduce the frequency of application, or to substitute a less potent steroid, and appropriate symptomatic treatment is indicated.

The steroid content of each tube is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Diprosone preparations contain the dipropionate ester of betamethasone which is a glucocorticoid exhibiting the general properties of corticosteroids.

In pharmacological doses, corticosteroids are used primarily for their anti-inflammatory and/or immune suppressive effects.

Topical corticosteroids such as betamethasone dipropionate are effective in the treatment of a range of dermatoses because of their anti-inflammatory, anti-pruritic and vasoconstrictive actions. However, while the physiologic, pharmacologic and clinical effects of the corticosteroids are well known, the exact mechanisms of their action in each disease are uncertain.

5.2 Pharmacokinetic properties

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of the epidermal barrier and the use of occlusive dressings.

Topical corticosteroids can be absorbed through intact, normal skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.
Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees, are metabolised primarily in the liver and excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Isopropyl alcohol
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

Polyethylene bottles containing 5ml, 30ml or 100ml of lotion with polyethylene screw caps, contained in a cardboard box.

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

Merck Sharp & Dohme Ireland (Human Health) Limited
Red Oak North
South County Business Park
Leopardstown
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1286/027/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first renewal: 25 April 1983

Date of last renewal: 16 March 2007

10 DATE OF REVISION OF THE TEXT

September 2014