Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

DiproSalic 0.05% w/w + 2% w/w Scalp Application

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

0.05 % w/w Betamethasone (as dipropionate)
2.00 % w/w Salicylic Acid.

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

Betamethasone Dipropionate is a synthetic fluorinated corticosteroid. In combination with salicylic acid it is indicated for the treatment of chronic lichenified eczema, lichen planus, lichen simplex and non bullous ichthyosiform erythroderma. It is also effective in the less responsive conditions such as psoriasis of the scalp and chronic plaque psoriasis of the hands and feet but excluding widespread plaque psoriasis.

Topical salicylic acid softens keratin, loosens cornified epithelium and desquamates the epidermis.

4.2 Posology and method of administration

Adults:

In most cases a few drops should be applied to the affected areas once or twice daily and massaged gently and thoroughly into the skin.
For some patients adequate maintenance therapy may be achieved with less frequent application.

It is recommended that DiproSalic preparations are prescribed for two weeks, and that treatment is reviewed at that time. The maximum weekly dose should not exceed 60g.

Children:

Dosage in children should be limited to 5 days.

4.3 Contraindications

Rosacea, acne, perioral dermatitis, perianal and genital pruritus. Hypersensitivity to any of the ingredients of the DiproSalic preparations contra-indicates their use as does tuberculous and most viral lesions of the skin, particularly herpes simplex, vaccinia, varicella. DiproSalic should not be used in napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

4.4 Special warnings and precautions for use

Occlusive dressings must not be used, since under these circumstances the keratolytic action of salicylic acid may lead to enhanced absorption of the steroid.

Local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. Long term continuous therapy should be avoided in all patients irrespective of age. If used in children or on the face courses should be limited to 5 days.

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. Avoid contact with eyes and mucous membranes.

There have been a few reports in the literature of the development 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.

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.

The systemic absorption of betamethasone dipropionate and salicylic acid may be increased if extensive body surface areas or skin folds are treated for prolonged periods or with excessive amounts of steroids. Suitable precautions should be taken in these circumstances, particularly with infants and children.

If irritation or sensitization develops with the use of Diprosalic Ointment and Lotion, treatment should be discontinued.

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

If excessive dryness or increased skin irritation develops, discontinue use of this preparation.

Visual disturbance may be reported with systemic and topical (including intranasal, inhaled and intraocular) 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 of visual disturbances which may include cataract, glaucoma or rare diseases such as central serious chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Paediatric Use: Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a large skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilloedema.

4.5 Interaction with other medicinal products and other forms of interactions

None stated.

4.6 Fertility, pregnancy and lactation

Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients.

Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or 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 stated.

4.8 Undesirable effects

Diprosalic skin preparations are generally well tolerated and side-effects are rare.

Adverse reactions that have been reported with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis and blurred vision (see also section 4.4).

The following may occur more frequently with the use of occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

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

In addition, prolonged use of salicylic acid preparations may cause dermatitis.

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 pituitary-adrenal functions resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism, including Cushing's disease.

Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised.

With topical preparations containing salicylic acid excessive prolonged use may result in symptoms of salicyclism. Treatment is symptomatic. Measures should be taken to rid the body rapidly of salicylate. Administer oral sodium bicarbonate to alkalinize the urine and force diuresis.

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

DiproSalic preparations contain the dipropionate ester of betamethasone which is a glucocorticoid exhibiting the general properties of corticosteroids, and salicylic acid which has keratolytic properties.

Salicylic acid is applied topically in the treatment of hyperkeratotic and scaling conditions where its keratolytic action facilitates penetration of the corticosteroid.

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

Salicylic acid exerts only local action after topical application.
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 pre-clinical 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

Disodium edetate
Hypromellose
Sodium hydroxide
Isopropyl alcohol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Polyethylene container with high density polyethylene closures, containing 30 ml or 100 ml of product.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Organon Pharma (Ireland) Limited
2 Dublin Landings
North Wall Quay - North Dock
D01 V4A3
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23198/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 October 1983

Date of last renewal: 16 March 2007

10 DATE OF REVISION OF THE TEXT

July 2021