1. NAME OF THE MEDICINAL PRODUCT
Diprosalic® Lotion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Betamethasone Dipropionate 0.64 mg/g*
(* equivalent to 0.5 mg/g Betamethasone)
Salicylic Acid 20 mg/g

3. PHARMACEUTICAL FORM
Cutaneous solution
A colorless, translucent, viscous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Betamethasone Dipropionate is a synthetic fluorinated corticosteroid.
Diprosalic Lotion provides anti inflammatory, antipruritic, anti allergic and chronic hyperkeratotic and dry keratolytic activity in the topical management of subacute dermatoses responsive to corticosteroid therapy.

4.2 Posology and method of administration
Adults:
Once to twice daily. In most cases a thin film should be applied to the affected areas 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 60 g.

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 presentations contra-indicates their use as does tuberculous and most viral lesions of the skin, particularly herpes simplex, vacinia, 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 special precautions for use
Occlusion 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. If used in children or on the face courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age.

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.

It is dangerous if Diprosalic presentations come into contact with the eyes. Avoid contact with the eyes and mucous membranes.

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 sensitisation develops with the use of Diprosalic, 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 serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

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.

Paediatric population: Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituary-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 papilledema.

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.

4.5 Interaction with other medicinal products and other forms of interaction
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.

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

Adverse reactions that have been reported with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis and allergic contact dermatitis.

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

Vision blurred (see also section 4.4) has been reported with corticosteroid use (frequency not known).

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).

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form :https://sideeffects.health.gov.il

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
Pharmacotherapeutic group: Betamethasone, ATC code: D07XC01

Betamethasone is classed as a potent corticosteroid (Class III).

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 metabolized 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 leaflet.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Isopropyl alcohol
Hydroxypropyl methylcellulose
Sodium hydroxide
Disodium edetate

Purified water

6.2 Incompatibilities
None stated.

6.3 Shelf life
The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage
Store not above 25°C
Do not use beyond 6 weeks from first opening.

6.5 Nature and contents of container
30 ml polyethylene containers with polypropylene closure.

6.6 Special precautions for disposal and other handling
Not applicable.

7. LICENSE HOLDER AND ADDRESS
Organon Pharma Israel Ltd., 1 Atir Yeda, Kfar Saba

8. REGISTRATION NUMBER
134.10.24243

9. MANUFACTURER
Organon LLC, NJ USA

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