SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE

DIPROSALIC® Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of DIPROSALIC Ointment contains 0,64 mg betamethasone dipropionate (equivalent to 0,5 mg of betamethasone) and 30 mg of salicylic acid.

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

A white, greasy ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

DIPROSALIC Ointment is indicated in the topical management of sub-acute and chronic hyperkeratotic and dry dermatoses responsive to corticosteroid therapy.

4.2 Posology and method of administration

A thin film of DIPROSALIC Ointment should be applied to cover the affected area completely. The ointment should be massaged gently and thoroughly into the skin. The usual frequency of application is twice daily. For some patients, adequate maintenance therapy may be achieved with less frequent application.

4.3 Contraindications

DIPROSALIC Ointment is contraindicated in the treatment of herpes simplex, vaccinia, or varicella.

DIPROSALIC Ointment is contraindicated in patients with a history of sensitivity reactions to any of its components.

4.4 Special warnings and precautions for use

DIPROSALIC Ointment is not for ophthalmic use. Avoid contact with eyes and mucous membranes.

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 continuous treatment with DIPROSALIC Ointment should be avoided as far as possible as this may cause atrophic changes in the skin leading to thinning, loss of elasticity, dilatation of superficial blood vessels, telangiectasia and ecchymoses. These changes are particularly likely to occur on the face and when occlusive dressings are used.

Systemic absorption of DIPROSALIC Ointment may occur, particularly under the following conditions: when large quantities are used, when application is made to wide areas of the body, to damaged skin and when the occlusive dressing technique is applied.
Depression of the hypothalamic-pituitary-adrenal axis with consequent suppression of the adrenal gland may occur. These effects are most likely to be severe in children. Growth may be retarded and a Cushingoid state may be produced. Benign intracranial hypertension has been rarely reported.

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

If a secondary microbial skin infection is present suitable concomitant antimicrobial therapy should be instituted.

DIPROSALIC Ointment should be used with particular caution in facial dermatoses, and only for short periods. A steroid rosacea-like facies may be produced.

DIPROSALIC Ointment should be used for short courses only. Regular review should be made of the necessity for continuing therapy.

DIPROSALIC Ointment should not be used in the nappy areas in infants for flexural eruptions and ideally should not be used in infants and young children at all.

The treatment of severe psoriasis with DIPROSALIC Ointment may provoke the pustular form of the disease.

DIPROSALIC Ointment should not be applied to any skin crease areas.

Discontinue temporarily if salicylic acid idiosyncrasy results in excessive dryness, increased irritation, or unwanted scaling.

Salicylic acid should not be used for prolonged periods, in high concentrations, on large areas of the body or on inflamed or broken skin. It should be used with care on the extremities of patients with impaired peripheral circulation and diabetics.

Long term continuous or inappropriate 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.

4.5 Interaction with other medicines and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

Pregnancy

Corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore, DIPROSALIC Ointment should not be used during pregnancy.

Breastfeeding

The use of DIPROSALIC Ointment is not recommended for mothers who are breastfeeding.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

If irritation or sensitisation develops with the use of DIPROSALIC Ointment, treatment should be discontinued.

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.

Systemic adverse reactions, such as blurred vision, have also been reported with the use of topical corticosteroids.

Salicylic acid is a mild irritant. Application of salicylic acid preparations to the skin may cause dermatitis.

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 medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

See WARNINGS AND SPECIAL PRECAUTIONS (section 4.4) and SIDE EFFECTS (section 4.8).

Symptoms: Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency, and produce manifestations of hypercorticism, including Cushing syndrome.

Excessive or prolonged use of topical salicylic acid may cause symptoms of salicylism, including dizziness, tinnitus, deafness, sweating, nausea and vomiting, headache, and mental confusion.

Treatment: Treatment is symptomatic and supportive. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

Measures should be taken to rid the body rapidly of salicylate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A.13.4.1 Corticosteroids with or without anti-infective agents

DIPROSALIC Ointment has anti-inflammatory, anti-allergic, antipruritic, keratolytic and desquamating properties.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin

White soft paraffin.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for Storage

Store at or below 25 °C. Protect from light.

6.5 Nature and contents of Container

Tubes of 20g.

6.6 Special Precautions for Disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Organon South Africa (Pty) Ltd

Spaces, 1st Floor

22 Magwa Crescent, Gateway West

Waterfall City, Midrand, 2090

South Africa

8 REGISTRATION NUMBER(S)

H/13.4.1/32

9 DATE OF FIRST AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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