SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE

DIPROSONE® Cream

DIPROSONE® Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of DIPROSONE Cream contains 0,64 mg betamethasone dipropionate (equivalent to 0,5 mg of betamethasone).

Each gram of DIPROSONE Ointment contains 0,64 mg betamethasone dipropionate (equivalent to 0,5 mg betamethasone).

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

DIPROSONE Cream: A smooth, white cream.

DIPROSONE Ointment: A smooth, white ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

DIPROSONE is indicated in corticosteroid-responsive skin diseases such as psoriasis and dermatoses, including the eczemas.

4.2 Posology and method of administration

A thin film of DIPROSONE should be applied to cover the affected area completely and should be massaged gently and thoroughly into the skin. The usual frequency of application is twice daily. Some patients require more or less frequent applications.

4.3 Contraindications

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

DIPROSONE is contraindicated in those patients with a history of sensitivity reactions to any of its components.

4.4 Special warnings and precautions for use

DIPROSONE is **not** for ophthalmic use.

If irritation or sensitisation develops with the use of DIPROSONE, treatment should be discontinued, and appropriate therapy instituted.

Long-term continuous treatment with DIPROSONE 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, telangiectasiae and ecchymoses. These changes are particularly likely to occur on the face and when occlusive dressings are used.

Systemic absorption of DIPROSONE may occur, particularly under the following conditions:

- when large quantities are used
- when application is made to wide areas of the body or 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.

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.

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

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

DIPROSONE should be used with caution near the eyes.

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

DIPROSONE 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 psoriasis with DIPROSONE may provoke the pustular form of the disease.

DIPROSONE should not be applied to any skin crease areas.

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 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 advice 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, DIPROSONE should not be used during pregnancy.

Breastfeeding

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

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

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

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

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 Special warnings and precautions for use (section 4.4) and Undesirable 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.

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

DIPROSONE has anti-inflammatory, antipruritic and vasoconstrictive actions.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

DIPROSONE Cream: a cream base containing Ceteth-20, cetostearyl alcohol, liquid paraffin, monobasic sodium phosphate, phosphoric acid, sodium hydroxide, white soft paraffin and purified water.

Preservative: Chlorocresol 0,1 % *m/m*

DIPROSONE Ointment: a base containing liquid paraffin and white soft paraffin.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

DIPROSONE Cream and Ointment: 36 months

6.4 Special precautions for Storage

Store at or below 25 °C.

6.5 Nature and contents of Container

DIPROSONE Cream: Tubes of 20g and 30g.

DIPROSONE Ointment: Tubes of 20g and 30g.

Not all pack sizes may be marketed.

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)

DIPROSONE Cream: F/13.4.1/17

DIPROSONE Ointment: F/13.4.1/18

9 DATE OF FIRST AUTHORISATION

Date of Registration:

DIPROSONE Cream: 24 April 1974

DIPROSONE Ointment: 18 January 1973

10 DATE OF REVISION OF THE TEXT

21 June 2024

S-CCDS-MK1460-DPS-MTL-082017; RCN100002505.

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Namibia Only: Diprosone Topical Cream	
Registration Number	90/13.4.1/001544
Scheduling Status	NS2

Botswana Only: Diprosone Cream	
Registration Number	BOT1202176A-B
Scheduling Status	S2

Namibia Only: Diprosone Topical Ointment	
Registration Number	90/13.4.1/001547
Scheduling Status	NS2

Botswana Only: Diprosone Ointment	
Registration Number	BOT1202232 & BOT1202332A
Scheduling Status	S2