

Product name: Diprosone cream and ointment	Components: English Professional Information
	SR-PIN: 19 December 2017

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

DIPROSONE[®] Cream

DIPROSONE[®] Ointment

COMPOSITION

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

Each gram of DIPROSONE Ointment contains 0,64 mg betamethasone dipropionate (equivalent to 0,5 mg betamethasone) in a base containing liquid paraffin and white soft paraffin.

PHARMACOLOGICAL CLASSIFICATION

A.13.4.1 Corticosteroids with or without anti-infective agents

PHARMACOLOGICAL ACTION

DIPROSONE has anti-inflammatory, antipruritic and vasoconstrictive actions.

INDICATIONS

AJ20171219		Page 1 of 6
-------------------	--	--------------------

Product name: Diprosone cream and ointment	Components: English Professional Information
	SR-PIN: 19 December 2017

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

CONTRAINDICATIONS

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

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

WARNINGS AND SPECIAL PRECAUTIONS

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, 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

Product name: Diprosone cream and ointment	Components: English Professional Information
	SR-PIN: 19 December 2017

be retarded and a Cushingoid state may be produced. Benign intracranial hypertension has rarely been 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.

Product name: Diprosone cream and ointment	Components: English Professional Information
	SR-PIN: 19 December 2017

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.

PREGNANCY AND LACTATION

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.

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

DOSAGE AND DIRECTIONS FOR USE

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.

SIDE 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.

Product name: Diprosone cream and ointment	Components: English Professional Information
	SR-PIN: 19 December 2017

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See **WARNINGS AND SPECIAL PRECAUTIONS** and **SIDE EFFECTS**.

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.

IDENTIFICATION

DIPROSONE Cream: A smooth, white cream.

DIPROSONE Ointment: A smooth, white ointment.

PRESENTATION

DIPROSONE Cream: Tubes of 20 g.

DIPROSONE Ointment: Tubes of 20 g.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Keep out of reach of children.

REGISTRATION NUMBERS

DIPROSONE Cream: F/13.4.1/17

AJ20171219		Page 5 of 6
-------------------	--	--------------------

Product name: Diprosone cream and ointment	Components: English Professional Information
	SR-PIN: 19 December 2017

DIPROSONE Ointment: F/13.4.1/18

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

MSD (Pty) Ltd

117 16th Road

Halfway House

1685

South Africa

DATE OF PUBLICATION

Date of registration :

DIPROSONE Cream: 24 April 1974

DIPROSONE Ointment: 18 January 1973

Revision: July 1983 (SR-PIN: 19 December 2017)

S-CCDS-MK1460-DPS-MTL-082017