Revision Date: 04-12-2023

SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE

DIPROGENTA® Cream

DIPROGENTA® Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of DIPROGENTA Cream contains 0,64 mg betamethasone dipropionate (equivalent to 0,5 mg of betamethasone) and 1,7 mg gentamicin sulphate (equivalent to 1 mg gentamicin).

Each gram of DIPROGENTA Ointment contains 0,64 mg betamethasone dipropionate (equivalent to 0,5 mg betamethasone) and 1,7 mg gentamicin sulphate (equivalent to 1 mg gentamicin).

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

DIPROGENTA Cream: A smooth, white cream.

DIPROGENTA Ointment: A smooth, off-white ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

DIPROGENTA is indicated in the topical treatment of corticosteroid-responsive dermatoses with suspected, or complicated by, secondary infection caused by organisms sensitive to gentamicin.

DIPROGENTA Cream is recommended for wet, oozing infections, and DIPROGENTA Ointment for more dry, scaly conditions.

4.2 Posology and method of administration

A thin film of DIPROGENTA should be massaged gently and thoroughly to cover the affected area completely twice daily, in the morning and at night. Some patients may achieve adequate maintenance therapy with less frequent application.

4.3 Contraindications

DIPROGENTA is contraindicated in the treatment of herpes simplex, vaccinia, varicella and tuberculosis of the skin.

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

4.4 Special warnings and precautions for use

DIPROGENTA is **not** for ophthalmic use.

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

Long-term continuous treatment with DIPROGENTA 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 topically applied corticosteroids such as those contained in DIPROGENTA 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.

Systemic absorption of topically applied gentamicin as contained in DIPROGENTA may be increased if extensive body surface areas are treated, especially over prolonged time periods or in the presence of dermal disruption. In these cases, the undesirable effects which occur following systemic use of gentamicin may potentially occur. Cautious use is recommended under these conditions, particularly in infants and children.

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

DIPROGENTA should be used with caution near the eyes.

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

DIPROGENTA 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 DIPROGENTA may provoke the pustular form of the disease.

DIPROGENTA should not be applied to any skin crease areas.

Prolonged use of topical DIPROGENTA may result in overgrowth of non-susceptible organisms, particularly fungi. If this occurs or if irritation, sensitisation or super-infection develops, treatment with DIPROGENTA should be discontinued and appropriate therapy instituted.

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 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 such as betamethasone 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, DIPROGENTA should not be used during pregnancy.

Breastfeeding

It is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk.

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

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Skin and subcutaneous tissue disorders: The following adverse reactions have been reported and the frequencies are unknown: burning, itching, irritation, transient irritation (erythema and pruritus), dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

Treatment with gentamicin has produced transient irritation (erythema and pruritus) that usually did not require discontinuance of treatment.

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

Systemic absorption of aminoglycosides such as gentamicin in DIPROGENTA, may be associated with ototoxicity.

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 providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions 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; manifestations of hypercorticism, including Cushing syndrome may occur.

Excessive prolonged use of topical gentamicin may lead to overgrowth of lesions by fungi or non-susceptible bacteria.

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

Appropriate antifungal or antibacterial therapy is indicated if overgrowth occurs.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Synthetic corticosteroid, betamethasone dipropionate has anti-inflammatory, anti-allergic and antipruritic activity. Topical gentamicin has a broad-spectrum antibacterial activity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

DIPROGENTA Cream: cream base of cetomacrogol 1 000, cetostearyl alcohol, liquid paraffin, monobasic sodium phosphate, phosphoric acid, white soft paraffin and purified water.

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

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

DIPROGENTA Cream: 36 months

DIPROGENTA Ointment: 36 months

6.4 Special precautions for Storage

Store at or below 25 °C.

6.5 Nature and contents of Container

DIPROGENTA Cream: Tubes of 20 g.

DIPROGENTA Ointment: Tubes of 20 g.

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)

DIPROGENTA Cream: F/13.4.1/223

DIPROGENTA Ointment: F/13.4.1/224

9 DATE OF FIRST AUTHORISATION

Date of Registration: 24 April 1974

Most recent revision: 23 July 2010 (SR-PIN:19 December 2017)

10 DATE OF REVISION OF THE TEXT

04 December 2023

S-CCDS-MK1460C-MTL-082017; RCN100002423; RCN100003442

Namibia Only: Diprogenta Cream	
Registration Number	90/13.4.1/001537
Scheduling Status	NS2

Botswana Only: Diprogenta Cream	
Registration Number	BOT1202175
Scheduling Status	S2

Namibia Only: Diprogenta Ointment	
Registration Number	90/13.4.1/001538
Scheduling Status	NS2

Botswana Only: Diprogenta Ointment	
Registration Number	B9325505

Scheduling Status	S2