# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

Diprosone® 0.5 mg/g Ointment

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredient is betamethasone. It is supplied as betamethasone dipropionate 0.64 mg/g, which corresponds to 0.5 mg/g of betamethasone.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Ointment

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Diprosone Ointment possess anti-inflammatory, antipruritic and antiallergic activity in the topical treatment of corticosteroid-responsive dermatoses such as: psoriasis, contact dermatitis (dermatitis venenata), atopic and allergic dermatitis, neurodermatitis (lichen simplex chronicus), lichen planus, eczema (nummular eczema, eczematous dermatitis included), dyshidrosis (pompholyx), seborrheic dermatitis, exfoliative dermatitis and stasis dermatitis.

As a general rule, corticosteroids should not be used in the treatment of banal conditions; their potency limits their use to serious cases in children.

### 4.2 Dosage and method of administration

Posology
Application once to twice daily, in the morning and/or at night.

*Paediatric population*
Children are more likely to experience systemic undesirable effects linked to the use of topically applied
corticosteroids and, in general, require shorter treatments with less powerful agents than adults. It is advisable to only apply the minimum amount necessary to gain a therapeutic effect. Corticoids may affect

growth hormone secretion in children; therefore, the evolution of their weight and height should be monitored.

Method of Administration
Diprosone Ointment should be applied twice daily, in an amount sufficient to completely cover the affected areas. A gentle massage enhances penetration. In some patients, a single application should suffice.

Maximum daily dose: use the minimum amount of Diprosone Ointment that has a therapeutic activity. At each application: cover the affected area with a thin layer of Diprosone Ointment.

It is recommended to wash your hands after applying Diprosone.

## 4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients.

Topical corticosteroids are contraindicated in case of bacterial or viral infection, especially in syphilitic and tuberculous conditions, smallpox, chickenpox, herpes zoster, herpes simplex, acne vulgaris and rosacea.

If, for exceptional reasons, corticosteroid therapy is still initiated, it should be subject to strict medical supervision because the microbial infection might spread. A topical or systemic, preventive or simultaneous antibiotic treatment should be indicated. If necessary, corticosteroid therapy should be discontinued on infected lesions.

Application on wounds and ulcers is contraindicated.

## 4.4 Special warnings and precautions for use

Treatment should be discontinued in case of severe irritation or serious sensitisation.

In case of bacterial infection, specific antimicrobial therapy should be initiated. If a favourable response to treatment does not occur quickly, the topical administration of corticosteroids should be suspended until the infection has been perfectly brought under control.

Diprosone cannot be applied on or near the eyes; it can be applied on mucous membranes.

Caution is required when applying Diprosone on atrophied skin.

Use on degraded or atrophied skin, over large areas of the skin, under

occlusive dressing and in children (because of the high body surface area/weight ratio and thinness of their skin) can increase systemic absorption.

Topical corticosteroids can give a distorted clinical picture. A rebound effect may occur after treatment is discontinued.
An infectious exacerbation may occur and wound healing may be slowed down.

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.

Paediatric population
Children can absorb larger amounts of corticosteroids (because of the high body surface area/weight ratio). Therefore, they are more susceptible to systemic effects (see the section "**Undesirable effects**"). Corticosteroids may influence the secretion of the growth hormone in children. Therefore, the evolution of their weight and height should be monitored.

Visual disturbance
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.

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

None known.

## 4.6 Pregnancy and breastfeeding

Pregnancy
There are no relevant and well-controlled clinical studies on the teratogenic potential of corticosteroids administered topically in pregnant women. Therefore, topical corticosteroids should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.

Use of topical corticosteroids may suppress hypothalamic-pituitary-adrenal axis, resulting in secondary adrenal function.

Breastfeeding
It is not known whether a topical administration of corticosteroids would result in sufficient systemic absorption for detectable amounts to pass into the breast milk. You should decide to either discontinue nursing or abstain from treatment with Diprosone by taking into account the benefit of breastfeeding for the child in relation to the treatment benefit for the woman.

## 4.7 Effects on ability to drive and use machines

Not relevant.

## 4.8 Undesirable effects

It is known that corticosteroids can be absorbed through the skin: the possibility of occurrence of systemic effects should be considered in patients on prolonged treatment or when treating a large area of the skin.
Systemic effects are expressed in part by the inhibition of the hypothalamic-pituitary-adrenal axis, and secondly by the Cushing-like activity of the product itself.

In children, the absorption capacity is greater; they are therefore more susceptible to systemic effects, even if they only use 30 g per week.

Patients with serious hepatic disorders are also more susceptible to these effects.
The likelihood of localised and systemic effects is enhanced if the skin is thin and degraded.

Given that corticosteroids may influence the secretion of the growth hormone in children, the evolution of their weight and height should be monitored.

The following adverse effects have been reported during treatment with corticosteroids: burning sensation, pruritus, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, atrophied skin, stretch marks and miliaria.

As with any product applied to the skin, an allergic reaction to Diprosone is not impossible.

The following adverse effects have been reported in children: inhibition of the hypothalamic-pituitary-adrenal axis, Cushing's syndrome, growth retardation and increased intracranial pressure.

Diprosone Ointment is colourless and does not stain clothing.

Vision blurred (see also section 4.4) has been reported with corticosteroid use (unknown frequency: cannot be estimated from available data).

Reporting of suspected adverse reactions:
Healthcare professionals are requested to report any suspected adverse reactions via Pharmacy and the Poisons Board, Pharmacovigilance Electronic Reporting System
(PvERS) https://pv.pharmacyboardkenya.org

### 4.9 Overdose

The use of topical corticosteroids may inhibit the pituitary-adrenal axis and result in secondary adrenal insufficiency.

Treatment is symptomatic. Acute symptoms of cortical hyperfunction are reversible. Electrolyte balance should be treated, if necessary. In case of chronic toxicity, treatment with corticosteroids should gradually be reduced.

In case of oral accidental ingestion, it should be treated in the same way as oral corticosteroid overdose.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, dermatological preparations - potent corticosteroids (Class III) (European standard), ATC code: D07A C01

1. Betamethasone dipropionate

Betamethasone dipropionate belongs to Class I of highly active corticosteroids (American standard).

Applied topically, it has a rapid and prolonged anti-inflammatory, antipruritic and vasoconstrictor activity.

Topical treatment with corticosteroids is never causal; consideration should be given to possible recurrence of the disease after discontinuation of treatment.

2. Excipients

The ointment is fatty excipient-based.

The occlusive effect of this fatty excipient enhances the absorption of betamethasone dipropionate.

### 5.2 Pharmacokinetic properties

Systemic absorption of betamethasone dipropionate is possible especially after prolonged treatment or when applied over large areas.

### 5.3 Preclinical safety data

Not applicable.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Liquid paraffin, petroleum jelly.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

3 years

### 6.4 Special precautions for storage

Keep out of the sight and reach of children.

Store at or below 30°C.

### 6.5 Nature and contents of container

Diprosone Ointment: available in aluminium tubes of 10, 15, 20, 30, 50, 100 and 500 g tubes.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

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22 Magwa Crescent
Gateway West
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2090
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## 8. MARKETING AUTHORISATION NUMBERS

1515

## 9. DATE OF FIRST AUTHORISATION

30/01/2026

## 10. DATE OF REVISION OF THE TEXT

02/02/2026