DATA SHEET

1. DIPROSONE®

DIPROSONE (0.05% w/w) cream
DIPROSONE (0.05% w/w) ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone dipropionate equivalent to betamethasone 0.5mg/g (0.05% w/w).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

DIPROSONE Cream is a white cream in a paraben-free water-washable vanishing cream base.
DIPROSONE Ointment is an off-white ointment in a preservative-free ointment base.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DIPROSONE is indicated for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. These include atopic eczema, infantile eczema, nummular eczema, contact dermatitis, neurodermatitis, anogenital and senile pruritus, lichen planus, intertrigo and psoriasis.

4.2 Dose and method of administration

DIPROSONE Cream and Ointment: Apply a small amount to the affected area twice daily. For some patients adequate maintenance therapy may be achieved with once daily application.

In most cases, 4 weeks continuous treatment should be considered the maximum.

Children: Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen.

4.3 Contraindications

Hypersensitivity to betamethasone dipropionate, other corticosteroids or any of the components. Like other topical corticosteroids, DIPROSONE preparations are contraindicated in viral infections of the skin, such as vaccinia, varicella and Herpes simplex, also tuberculosis, acne rosacea, fungal skin infections (moniliasis), perioral dermatitis and ulcerative conditions.

4.4 Special warnings and precautions for use

DIPROSONE preparations should not be used in or near the eyes.

If irritation or sensitisation develops, treatment should be discontinued and appropriate therapy instituted.

In the presence of an infection, an appropriate antifungal or antibacterial agent should be administered. If a favourable response does not occur within a few days to a week, DIPROSONE should be discontinued until the infection has been controlled adequately.

Corticosteroids are known to be absorbed percutaneously, therefore in patients under prolonged and extensive topical treatment, the possibility of systemic effects should be kept in mind.

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.

Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression
Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids. If either of the above are observed, withdraw the drug gradually by reducing the frequency of application, or by substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency.

Risk factors for increased systemic effects are:

- Potency and formulation of topical steroid
- Duration of exposure
- Application to a large surface area
- Use on occluded areas of skin e.g. on intertriginous areas or under occlusive dressings (in infants the nappy may act as an occlusive dressing)
- Use on thin skin areas such as the face
- Use on broken skin or other conditions where the skin barrier may be impaired
- Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.
- Patients applying large doses of potent topical corticosteroids over large body surface areas should be evaluated periodically for evidence of HPA axis suppression Patients applying doses of DIPROSONE in excess of 15g per day should be carefully monitored.
- In comparison with adults, children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects. This is because children have an immature skin barrier and a greater surface area to body weight ratio compared with adults.

Suitable precautions should be taken when using topical corticosteroids in patients with stasis dermatitis and other skin diseases with impaired circulation.

Prolonged use on flexures and intertriginous areas is undesirable.

Topical corticosteroid preparations may produce striae or atrophy of the skin or subcutaneous tissue. If this occurs, treatment should be discontinued. In most cases, four weeks continuous treatment should be considered the maximum.

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.

Use in Children

Chronic corticosteroid therapy may interfere with the growth and development of children. Babies and children up to four years should not be treated with topical steroids for longer than three weeks. In infants the napkins may act as an occlusive dressing and increase absorption.

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a larger skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilloedema.

4.5 Interaction with other medicines and other forms of interaction

No data available.

4.6 Fertility, pregnancy and lactation

Use in Pregnancy

Topical corticosteroids should not be used extensively on pregnant patients in large amounts or for prolonged periods of time.

Use in Lactation

Due to lack of data on the safety of betamethasone dipropionate in lactation, care should be exercised to ensure that the potential benefits to the lactating mother outweigh the possible hazards to the nursing infant.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The following adverse reactions have been reported with the use of topical corticosteroids: itching, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of skin, secondary infection, striae and miliaria.

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

Rarely reported adverse effects include tingling, prickly skin/tightening or cracking of skin, warm feeling, laminar scaling and perilesional scaling, follicular rash, skin atrophy, erythema and telangiectasia.

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: https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

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

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

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACEUTICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: betamethasone: ATC code: D07AC01

Betamethasone dipropionate is a potent topically active corticosteroid producing prompt and marked anti-inflammatory, anti-pruritic and vasoconstrictive effects.

According to the McKenzie-Stoughton Vasoconstrictor Test, betamethasone dipropionate was demonstrated to be significantly more active ($p<0.05$) than betamethasone valerate, fluocortolone and flumethasone pivalate. While the direct applicability of this vasoconstrictor test to clinical situations has not been demonstrated conclusively, the results showed betamethasone dipropionate to be active in a concentration of 0.000016%, the lowest concentration tested which showed activity.

5.2 Pharmacokinetic properties

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of the epidermal barrier and the use of occlusive dressings. While topical corticosteroids can be absorbed from normal intact skin, dermal inflammation and/or other dermatological disease processes may increase percutaneous absorption. Occlusive dressings also substantially increase percutaneous absorption.

After dermal absorption, topical corticosteroids enter pharmacokinetic pathways similar to those of systemically administered corticosteroids. In varying degrees, corticosteroids are bound to plasma proteins. They are metabolised primarily in the liver and excreted by the kidneys. Some topical corticosteroids and their metabolites undergo biliary excretion.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the Data Sheet.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

DIPROSONE Cream:

- chlorocresol 1mg/g as preservative
- soft white paraffin
- liquid paraffin
- cetostearyl alcohol
- cetomacrogol 1000

- sodium phosphate monobasic dehydrate
- phosphoric acid and
- purified water.

DIPROSONE Ointment:
- soft white paraffin and
- liquid paraffin.

6.2 Incompatabilities
None known.

6.3 Shelf life
Cream: 24 months from date of manufacture
Ointment: 36 months from date of manufacture

6.4 Special precautions for storage
Store below 25°C

6.5 Nature and contents of container
Cream: 15g and 50g tube

Ointment: 15g and 50g tube

6.6 Special precautions for disposal
Not applicable.

7. MEDICINE SCHEDULE
Prescription medicine

8. SPONSOR
Organon (New Zealand) Limited

Level 7, 36 Brandon Street

Wellington 6011

Tel: 0800 111 700

9. DATE OF FIRST APPROVAL
Cream: 10 June 1976
Ointment: 27 September 1976

10. DATE OF REVISION OF THE TEXT
20 January 2022

SUMMARY TABLE OF CHANGES

Section Changed	Change
4.4	Addition of text regarding HPA-axis suppression and reorganization of existing related information under this sub-heading.