AUSTRALIAN PRODUCT INFORMATION
DIPROVANT™ (betamethasone dipropionate)
Cream and Ointment

1 NAME OF THE MEDICINE

Betamethasone dipropionate.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

DIPROVANT™ Cream (0.05% w/w): Each gram contains betamethasone dipropionate equivalent to betamethasone 0.5 mg.

DIPROVANT™ Ointment (0.05% w/w): Each gram contains betamethasone dipropionate equivalent to betamethasone 0.5 mg.

For the full list of excipients, see **Section 6.1 List of Excipients**.

3 PHARMACEUTICAL FORM

DIPROVANT™ cream is supplied as a white, smooth, soft, homogenous cream, free of agglomerates and foreign matter.

DIPROVANT™ ointment is supplied as a white, smooth, soft, homogenous ointment, free of foreign matter.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

DIPROVANT™ is indicated for the relief of the 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

DIPROVANT™ Cream, 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.

DIPROVANT™ (betamethasone dipropionate) is not registered in a lotion dosage form. If a lotion is considered the most clinically appropriate dosage form of betamethasone dipropionate for the relief of the inflammatory and pruritic manifestations of a corticosteroid-responsive dermatosis, a different brand of betamethasone dipropionate will be required.

4.3 CONTRAINDICATIONS

Hypersensitivity to betamethasone dipropionate, other corticosteroids or any components in **DIPROVANT™**. Like other topical corticosteroids, **DIPROVANT™** is contraindicated in most viral infections of the skin, such as vaccinia, varicella, Herpes simplex and also tuberculosis and acne rosacea.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

DIPROVANT™ 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 promptly, **DIPROVANT™** 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. This applies particularly when using the occlusive dressing technique.

Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.

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.

Patients applying large doses of potent topical corticosteroids over large body surface areas should be evaluated periodically for evidence of HPA axis suppression. Manifestations of Cushing's syndrome also can be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients applying doses of **DIPROVANT™** in excess of 15 g per day should be carefully monitored.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of corticosteroid withdrawal may occur, requiring supplemental systemic corticosteroid therapy.

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

Topical corticosteroid preparations may produce striae or atrophy of the skin or subcutaneous tissue. If this occurs, treatment should be discontinued.

In most cases, 4 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 the elderly

No data available.

Paediatric use

Chronic corticosteroid therapy may interfere with the growth and development of children.

Paediatric patients may demonstrate greater susceptibility than mature patients to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects 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.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No data available.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy

(Category B3)

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

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

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

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.

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

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

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 toxicity, slow withdrawal of corticosteroids is advised.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Betamethasone dipropionate is a potent topically-active corticosteroid producing prompt, marked and prolonged 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.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

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 dermatologic disease processed may increase percutaneous absorption. Occlusive dressings also substantially increase percutaneous absorption.

Distribution

After dermal absorption, topical corticosteroids enter pharmacokinetic pathways similar to those of systemically administered corticosteroids. In varying degrees, corticosteroids are bound to plasma proteins.

Metabolism

Corticosteroids are metabolised primarily in the liver.

Excretion

Corticosteroids are excreted by the kidneys. Some topical corticosteroids and their metabolites undergo biliary excretion.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Cream
chlorocresol
white soft paraffin
liquid paraffin
cetostearyl alcohol
cetomacrogol 1000
monobasic sodium phosphate dihydrate
phosphoric acid
purified water

Ointment
white soft paraffin
liquid paraffin

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

The expiry date can be found on the packaging. In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG).

Use within 30 days after opening.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Cream and Ointment: Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Cream: 15 g and 50 g aluminium tubes.

Ointment: 15 g and 50 g aluminium tubes.

Not all pack sizes may be available.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

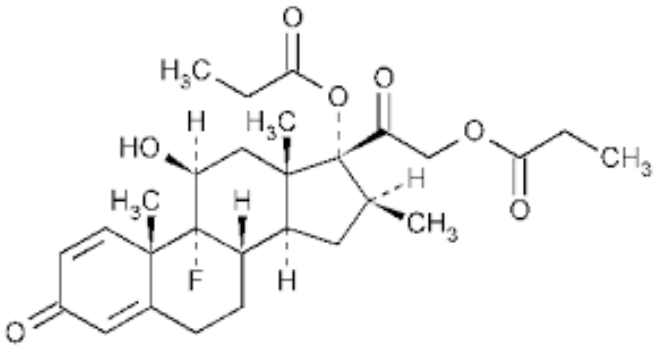
6.7 PHYSICOCHEMICAL PROPERTIES

Betamethasone dipropionate is a white or almost white, crystalline powder, practically insoluble in water, freely soluble in acetone and in methylene chloride, sparingly soluble in ethanol (96 per cent). The chemical name is 9-fluoro-11β-hydroxy-16β-methyl-3,20-dioxopregna-1,4-diene-17,21-diyl dipropanoate.

The empirical formula is $C_{28}H_{37}FO_7$.

Molecular Weight = 504.6

Chemical structure



CAS number

5593-20-4

7 MEDICINE SCHEDULE (POISONS STANDARD)

Prescription Only Medicine (Schedule 4)

8 SPONSOR

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9 DATE OF FIRST APPROVAL

10 Oct 2025

10 DATE OF REVISION

N/A

Summary Table of Changes

Section Changed	Summary of new information
all	new Product Information