AUSTRALIAN PRODUCT INFORMATION
DERMAID 1% CREAM (HYDROCORTISONE CREAM)
DERMAID 0.5% CREAM (HYDROCORTISONE CREAM)

1 NAME OF THE MEDICINE

Hydrocortisone.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

DermAid 1% cream. Hydrocortisone 1% w/w (10mg/g).
DermAid 0.5% cream. Hydrocortisone 0.5% w/w (5mg/g).

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

3 PHARMACEUTICAL FORM

DermAid cream is a white non-greasy cream for topical application.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

DermAid Cream is indicated for topical application for the temporary relief of symptoms associated with acute and chronic corticosteroid responsive conditions including: minor skin irritations, itching and rashes due to eczema, dermatitis, contact dermatitis (such as rashes due to cosmetics and jewellery), psoriasis, anogenital pruritus and sunburn.

4.2 DOSE AND METHOD OF ADMINISTRATION

DermAid 0.5% Cream. A thin layer should be applied to the affected skin one to three times a day as required.

DermAid 1% Cream. A thin layer should be applied to the affected skin one to two times a day as required. Once inflammation has subsided the frequency of use may be reduced.

4.3 CONTRAINDICATIONS

Like all other topical corticosteroids, DermAid Cream is contraindicated in vaccinia, chicken pox, herpes and other viral infections, bacterial infections, tuberculosis of the skin and syphilitic skin disorders.

Do not use in the eye.

Hypersensitivity to hydrocortisone, other corticosteroids or any other ingredient in the product.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

For external use only.

Long-term continuous topical therapy should be avoided where possible, particularly in children, as adrenal suppression can occur (even without occlusion).

As with other topical corticosteroids, when extensive areas are treated, sufficient systemic absorption may occur to produce the features of hypercorticalism. This effect is more likely to result if occlusive dressings are used or if treatment is prolonged. Rarely, local atrophy or striae may occur after prolonged treatment. This must be borne in mind when treating conditions such as severe eczema and seborrheic dermatitis. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye as glaucoma may result. Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions that have become infected.

Any spread of the infection requires withdrawal of corticosteroid therapy and systemic administration of antimicrobial agents. Bacterial infection is encouraged by the warm, moist conditions associated by occlusive dressings, so the skin should be cleansed prior to a fresh dressing being applied.

Patients in whom there is a risk of increased systemic absorption should be regularly evaluated for evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression by using urinary free cortisol (hydrocortisone) tests and monitoring morning plasma cortisol levels.

If there is evidence of suppression, attempts should be made to withdraw the drug or reduce the frequency of application. If hypersensitivity occurs, stop application and institute appropriate therapy. If irritation occurs, discontinue use. Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if occlusion is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated.

Hydrocortisone may mask signs of infection. If any infection is present, an appropriate anti-infective agent should be used first. DermAid Cream may be used to reduce inflammation but if a favourable response does not occur promptly then use of the product should be discontinued until the infection has been adequately controlled.

Use of the product near the eyes should be avoided. If any skin irritation develops discontinue use and treat appropriately. If extensive areas are treated, or if occlusive dressings are used, the possibility also exists of increased systemic absorption and this in turn could lead to the depression of the hypothalamo-pituitary-adrenal axis. In all such patients, it is essential to monitor adrenal function at regular intervals.

Use in the elderly
No data available.

Paediatric use

The risk of systemic absorption, and hence systemic toxicity, is greater in children due to a larger skin surface to body weight ratio than adults. The preparation is not recommended for use in children under 2 years of age except on the advice of a doctor.

Effects on laboratory tests

No data available.

Visual Disturbance

Visual disturbance may be reported with systemic and topical 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 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 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No interactions known.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy – Pregnancy Category A

Category A: Drugs which have been taken by a large number of pregnant women and women of child bearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

Use in lactation

It is not known whether sufficient absorption of topical corticosteroids takes place to be excreted in breast milk. The potential benefits should be weighed against possible hazards to the breastfeeding 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)

After the application of DermAid Cream a slight stinging sensation may occasionally be noticed. This transient symptom is most likely to disappear after several applications.

The following adverse effects have been reported with topical steroids: burning; itching; irritation; skin atropy; secondary infection; dryness; acneform eruptions and hypo-pigmentation. Treatment should be chiefly symptomatic and administration of the steroid should be discontinued.

Intolerance to the occlusive dressing (Miliary eruptions, folliculitis) may be expected to be observed, as with other corticosteroids. In such cases the use of an occlusive dressing should be discontinued. Use of the steroid may also need to be reduced or discontinued as local atrophy and striae of the skin may be observed.

In long-term treatment of extensive skin areas with occlusive dressings, one should bear in mind the possibility of inhibition of adrenal function. Therefore, adrenal function should be monitored under these circumstances.

Systemic adverse reactions, such as blurred vision, have also been reported with the use of topical corticosteroids (see also section 4.4 Special warnings and precautions for use – Visual Disturbance)

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

Percutaneous absorption of corticocosteroids may occur, especially under occlusive conditions. The following adverse effects have been reported with topical steroids: burning; itching; irritation; skin atrophy; secondary infection; dryness; acneform eruptions and hypo-pigmentation. Treatment should be chiefly symptomatic and administration of the steroid should be discontinued.

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

DermAid Cream contains dissolved hydrocortisone. Creams with dissolved hydrocortisone have been shown to be pharmacologically more active than creams with suspended hydrocortisone in causing vasoconstriction, as shown in a study by R. Woodford and B.W. Barry, U.K., 1984-5. The active component, hydrocortisone, has anti-inflammatory, anti-eczematous, anti-allergic and anti-pruritic properties.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Metabolism
Hydrocortisone is metabolised in the liver most likely by reduction of the 5,6 double bond and the C3 and C20 keto groups. The resultant hydroxy derivatives are then conjugated with glucuronic acid. Cortisone, an 11-keto-steroid is formed from hydrocortisone; the 11-keto-steroid is formed from hydrocortisone; the 11-keto-steroids are then reduced and conjugated to yield glucuronide metabolites. A small percentage of hydrocortisone is converted to the 17-keto-steroid. The C21 hydroxyl group is conjugated with sulphate.

Excretion

When radioactive-carbon, ring-labelled steroids are injected intravenously in man, most of the radioisotope is recovered in the urine within 72 hours. Neither biliary nor faecal excretion is of any quantitative importance in man. It has been estimated that the liver metabolises at least 70% of the hydrocortisone secreted.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Each gram of **DermAid cream** contains hydrocortisone (10mg/g or 5mg/g, as appropriate) in a cream base of purified water, macrogol 400, propylene glycol, cetyl alcohol, self-emulsifying glyceryl monostearate, benzyl alcohol, cetostearyl alcohol and cetomacrogol 1000.

6.2 INCOMPATIBILITIES

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

6.3 SHELF LIFE

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

6.4 SPECIAL PRECAUTIONS FOR STORAGE

DermAid 0.5% cream: Store below 25°C. Do not refrigerate.
DermAid 1% cream: Store below 25°C. Do not refrigerate.

6.5 NATURE AND CONTENTS OF CONTAINER

DermAid 0.5% cream: 30g laminate tube with a tamper evident seal packed into a carton.

DermAid 1% cream: 15g*, 30g laminate tube with a tamper evident seal packed into a carton.

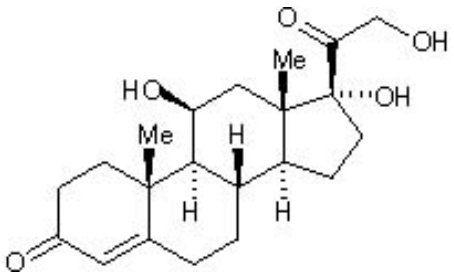
*Not currently available.

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

Chemical structure



CAS number

50-23-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

S2 (0.5%); S3 (1%)

8 SPONSOR

Ego Pharmaceuticals Pty Ltd.
21-31 Malcolm Road, Braeside, Victoria 3195
AUSTRALIA (ACN 005 142 361)

9 DATE OF FIRST APPROVAL

DermAid 0.5% cream: 2/8/1991

DermAid 1% cream: 27/8/1999

10 DATE OF REVISION

24 May 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.3	Contraindications: 'bacterial infections' added.
4.4	Addition of text 'For external use only'. Special Warnings and Precautions for use: safety-related request, addition of visual disturbance precautions/
4.8	Safety-related request, 'Systemic adverse reactions, such as blurred vision, have also been reported with the use of topical corticosteroids' added.