AUSTRALIAN PRODUCT INFORMATION
DERMAID 1% SOLUTION (HYDROCORTISONE)

1 NAME OF THE MEDICINE

Hydrocortisone.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone 1% w/w (10mg/g).

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

3 PHARMACEUTICAL FORM

DermAid 1% solution is a clear liquid for topical application.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For temporary relief of minor skin irritations, itching and rashes due to eczema, dermatitis, cosmetics, jewellery, insect bites, psoriasis, itching genital and anal areas, sunburn and other corticosteroid responsive conditions/dermatoses.

4.2 DOSE AND METHOD OF ADMINISTRATION

Apply a few drops of the solution to the affected area, 2-3 times daily as required. Massage in gently.

Once inflammation has subsided the frequency of use should be reduced to a minimum.

4.3 CONTRAINDICATIONS

Like all other topical corticosteroids, DermAid 1% solution is contraindicated in vaccinia, chicken pox, herpes and other viral infections, bacterial infections, tuberculosis of the skin, syphilitic skin disorders and acne.

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 1% solution 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 could in turn 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

DermAid 1% solution can safely be used by the elderly.

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 or pharmacist.

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 data available.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy – Pregnancy Category A

DermAid 1% solution can be used during pregnancy. Hydrocortisone is classified as a Category A drug in pregnancy. Category A drugs have been taken by a large number of pregnant women and women of child bearing age without any proven increase in frequency of malformations or other direct or indirect harmful effects on the foetus being observed.[i] Human placental transfer has been demonstrated; however limited foetal exposure occurs due to hydrocortisone inactivation by the placenta. Blood glucose levels should be monitored, as there is a risk of hyperglycaemia, especially in women with diabetes.

Use in lactation

DermAid 1% solution can be used while breastfeeding.

Hydrocortisone: Limited human data exist for the use of hydrocortisone in lactation. Trace amounts of endogenous hydrocortisone are excreted in breast milk. No reports describing the excretion of exogenous hydrocortisone into breast milk have been located. It is unlikely that these agents pose a risk to nursing infants. A review has shown that hydrocortisone has been safely used during lactation.[ii] The potential benefits should be weighed against the 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 1% solution 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 atrophy; secondary infection; dryness; acneform eruptions and hypo-pigmentation.

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

At the level used in DermAid 1% solution, hydrocortisone is classed as a mild potency corticosteroid.[1] Hydrocortisone has anti-inflammatory, anti-eczematous, anti-allergic and anti-pruritic properties.[2,3] The adrenal cortex produces a number of steroids which may be divided into glucocorticoids, mineralocorticoids and sex corticoids.[4] Hydrocortisone is produced by the adrenal cortex and is a glucocorticoid which, together with mineralocorticoids, are collectively known as corticosteroids.

[1] Kligman AM, Frosch PJ. Steroid Addiction. International Journal of Dermatology 1979;18(1):23-31.
[2] The Merck Index 12th Edition. NJ, USA: Merck Research Laboratories; 1996. Hydrocortisone. p 819-820.
[3] Martindale. 35th Edition. London, UK: Pharmaceutical Press; 1994. Hydrocortisone. p. 901-907.
[4] Feldmann RJ, Maibach HI. Percutaneous penetration of steroids in man. J Invest Dermatol. 1969;52(1):89-94.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption
Percutaneous penetration of corticosteroids varies among the individual patients and can be increased by the use of occlusive dressings, by increasing the concentration of the corticosteroid, and by using different vehicles. The use of an occlusive dressing with hydrocortisone for 96 hours substantially enhances percutaneous penetration of the drug; however, such use for up to 24 hours does not appear to alter penetration of topically

applied hydrocortisone. Following topical application of a corticosteroid to most areas of normal skin, only minimal amounts of the drug reach the dermis and subsequently the systemic circulation; however, absorption is markedly increased when the skin has lost its keratin layer and can be increased by inflammation and/or diseases of the epidermal barrier (e.g., psoriasis, eczema). The drugs are absorbed to a greater degree from the scrotum, axilla, eyelid, face, and scalp than from the forearm, knee, elbow, palm, and sole. Even after washing the area being treated, prolonged absorption of the corticosteroid occurs, possibly because the drug is retained in the stratum corneum.

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 hydroxyderivatives 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 humans, 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 1% solution** contains hydrocortisone 10mg in a solution base of purified water, hexylene glycol, phenoxyethanol and anhydrous citric acid.

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

Store below 30°C.

6.5 NATURE AND CONTENTS OF CONTAINER

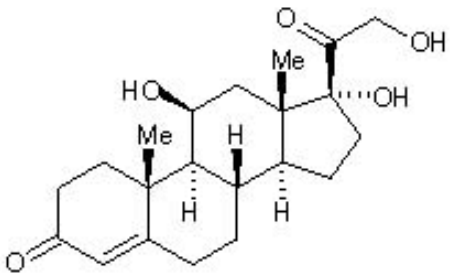
30mL HDPE bottle fitted with a dropper and packed into a carton.

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)

S3

8 SPONSOR

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

9 DATE OF FIRST APPROVAL

29 September 2015.

10 DATE OF REVISION

23 May 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.4	'Special Warnings and Precautions for use': safety-related request, addition of visual disturbance precautionary statement.
4.8	'Adverse effects (undesirable effects)': Safety-related request, 'Systemic adverse reactions, such as blurred vision, have also been reported with the use of topical corticosteroids' added.

[i] In M. Drugs in Pregnancy. Melbourne, Australia: The Royal Women's Hospital Pharmacy Department; 2006.

[ii] Briggs GG, Freeman RK, Yaffe SJ, editors. Drugs in Pregnancy and Lacation. 7th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2005.