New Zealand Data Sheet

1. PRODUCT NAME

DermAid® Soft Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

DermAid Soft 0.5% Cream (0.5% w/w hydrocortisone)
DermAid Soft 1.0% Cream (1.0% w/w hydrocortisone)

Excipient(s) with known effect

DermAid Soft Cream contains cetostearyl alcohol.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Topical cream.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

DermAid Soft 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 soap, detergent, cosmetics and jewellery), psoriasis, non-infected anogenital pruritus and sunburn.

4.2. Dose and method of administration

A thin layer should be applied to the affected skin two to four times a day. Once the inflammation has subsided the frequency may be reduced.

In atopic dermatitis (eczema), a rebound of pre-existing dermatoses can occur with abrupt discontinuation of topical corticosteroid preparations. Therapy with topical corticosteroids should be gradually discontinued once control is achieved and an emollient continued as maintenance therapy

4.3. Contraindications

Acne.

Hypersensitivity to any of the ingredients.

Do not use in the eye.

Like all other topical corticosteroids, DermAid Soft Cream is contraindicated in skin infections and infestations such as chickenpox, herpes and other viral infections.

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

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 for 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.

4.4. Special warnings and precautions for use

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 seborrhoeic 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.

Topical corticosteroids should be used with caution in patients with primary skin infections. 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 hypothalmic-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.

Withdrawal of corticosteroid therapy may exacerbate psoriasis. The frequency of application should be reduced before withdrawing the therapy. Therapy may be continued with a milder preparation such as Egoderm Cream or Ointment.

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.

Paediatric population

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.

4.5. Interaction with other medicines and other forms of interaction

None known.

4.6. Fertility, pregnancy and lactation

Fertility

No data available.

Pregnancy

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.

Breast-feeding

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

None known.

4.8. Undesirable effects

General disorders and administration site conditions

“Rebound effect”, see section 4.2.

Skin and Subcutaneous Tissue Disorders

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

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.

Other

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 Section 4.4.

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

4.9. Overdose

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

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

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, weak (group I); ATC code: D07A A02

DermAid Soft Cream contains hydrocortisone.

Mechanism of action

5.2. The active component, hydrocortisone, has anti-inflammatory, anti-eczematous, anti-allergic and anti-pruritic properties.Pharmacokinetic properties

Absorption

Hydrocortisone is absorbed through the skin allowing penetration to the deeper layers. The extent of absorption is greater for inflamed skin and other skin conditions such as eczema and psoriasis. Absorption is also greater in areas such as the ear, scrotum, axillae, face and scalp. Absorption is

aided by occlusive dressings due to the resulting hydration of the skin. Once absorbed, the pharmacokinetics are similar to systemic steroids.

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-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

No specific data available.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

DermAid Soft Cream contains: 1,3-butylene glycol, cetostearyl alcohol, citric acid, dimeticone 350, disodium edetate, self-emulsifying glyceryl monostearate, light liquid paraffin, PEG-40 stearate, povidone, dibasic anhydrous sodium phosphate, purified water, xanthan gum and phenethyl alcohol (as preservative).

6.2. Incompatibilities

None known.

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Store at or below 25°C.

6.5. Nature and contents of container

Tube, plastic, 15g and 30g.

Not all strengths or pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

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

7. MEDICINE SCHEDULE

DermAid Soft 0.5% Cream: Pharmacy Only Medicine
DermAid Soft 1.0% Cream: Pharmacist Only Medicine

8. SPONSOR

Douglas Pharmaceuticals Ltd
P O Box 45 027
Auckland 0651
New Zealand
Phone: (09) 835 0660

9. DATE OF FIRST APPROVAL

26 July 2001

10. DATE OF REVISION OF THE TEXT

24 February 2022
Summary table of changes

Section Changed	Summary of new information
4.1	Editorial updates
4.2	Added precaution regarding rebound effect per Medsafe's request
4.3	Editorial updates
4.8	Addition of headings Addition of information regarding rebound effect as per Medsafe's request Addition of information regarding blurred vision.
5.1	Mechanism of action added as per Reference Product information.
5.2	Addition of headings