DermAid Cream

Hydrocortisone

PRODUCT INFORMATION

NAME OF THE DRUG

DermAid Cream is available in two strengths:

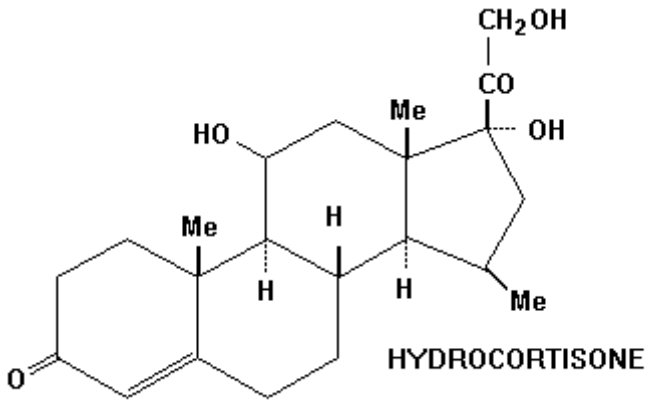
DermAid 0.5% Cream (0.5% w/w hydrocortisone)

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

DESCRIPTION

Physical characteristics: DermAid Cream contains hydrocortisone dissolved in a non-greasy white cream. It contains the inactives: water, cetomacrogol 1000, cetostearyl alcohol, cetyl alcohol, self emulsifying glyceryl monostearate, macrogol 400, propylene glycol and benzyl alcohol (as preservative).

Chemical characteristics: Hydrocortisone is a corticosteroid. The structural formula is:-



HYDROCORTISONE

CAS No. 50-23-7

Chemical name: 11β,17α,21-trihydroxypregn-4-ene-3,20-dione. Empirical formula: $C_{21}H_{30}O_5$.

PHARMACOLOGY

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.

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.

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.

CONTRAINDICATIONS

Like all other topical corticosteroids, DermAid Cream is contraindicated in vaccinia, chicken pox, herpes and other viral 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.

PRECAUTIONS

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.

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.

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 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 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.

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.

USE IN CHILDREN

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.

Interactions with other drugs

No interactions known.

ADVERSE REACTIONS

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 atrophy; 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.

DOSAGE AND 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 the inflammation has subsided the frequency of use may be reduced.

OVERDOSAGE

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; acneform eruptions and hypo-pigmentation. Treatment should be chiefly symptomatic and administration of the steroid should be discontinued.

PRESENTATION

Cream 0.5%w/w, 1%w/w (non-greasy, white): 30g tubes

STORAGE

Store below 25°C. Do not refrigerate.

POISONS SCHEDULE

S2 (0.5%); S3 (1%)

NAME AND ADDRESS OF THE SPONSOR

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

AUST R 10605 DermAid 0.5% Cream
AUST R 70706 DermAid 1% Cream
Date prepared: August 1999.
Date of amendment: January 2004.