DermAid 1% solution

Hydrocortisone

PRODUCT INFORMATION

NAME OF THE MEDICINE

DermAid 1% solution

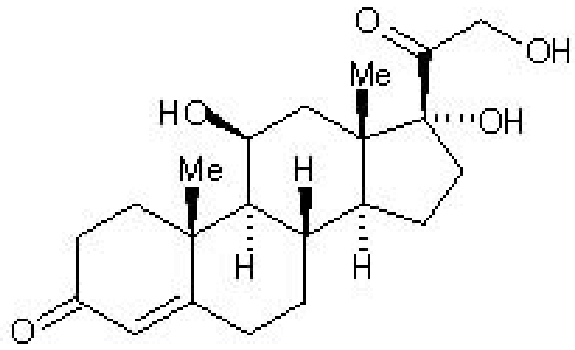
COMPOSITION

Active: 1% w/w hydrocortisone
Inactive: Purified water, hexylene glycol, phenoxyethanol and anhydrous citric acid.

DESCRIPTION

DermAid 1% solution contain hydrocortisone.

The structural formula of hydrocortisone is:



CAS No. 50-23-7 Molecular weight: 362.5

Chemical name: 11β,17α,21-trihydroxypregn-4-ene-3,20-dione.

Physical characteristics: Hydrocortisone is a white or almost white crystalline powder which is practically insoluble in water, sparingly soluble in acetone and in ethanol (96 percent) and slightly soluble in methylene chloride.

PHARMACOLOGY

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.

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 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

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.

CONTRAINDICATIONS

Like all other topical corticosteroids, DermAid 1% solution is contraindicated in vaccinia, chicken pox, herpes and other viral infections, bacterial skin 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.

PRECAUTIONS

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 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 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 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.[5] 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.[6] The potential benefits should be weighed against the 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 or pharmacist.

USE IN THE ELDERLY

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

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

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

ADVERSE REACTIONS

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.

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.

DOSAGE AND 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.

PRESENTATION

DermAid 1% solution is a clear liquid containing 1% w/w hydrocortisone.
30mL HDPE bottle fitted with a dropper and packed into a carton.

STORAGE

Store below 30°C.

POISON SCHEDULE

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NAME AND ADDRESS OF THE SPONSOR

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DermAid 1% solution AUST R 260373

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