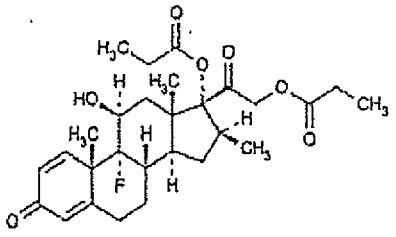
PRODUCT INFORMATION

DIPROSONE CREAM, OINTMENT AND LOTION

NAME OF THE DRUG

Betamethasone dipropionate equivalent to betamethasone 0.5 mg/g (0.05% w/w)

Chemical Structure:



Betamethasone dipropionate is 9-fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate. The empirical formula is $C_{28}H_{37}FO_7$. MW = 504.6

DESCRIPTION

Diprosone Cream (0.05% w/w): Each g contains betamethasone dipropionate equivalent to betamethasone 0.5 mg. The cream base consists of chlorocresol 1 mg/g as preservative, soft white paraffin, liquid paraffin, cetostearyl alcohol, cetomacrogol 1000, sodium phosphate monobasic, phosphoric acid and purified water.

Diprosone Ointment (0.05% w/w): Each g contains betamethasone dipropionate equivalent to betamethasone 0.5 mg in an ointment base consisting of soft white paraffin and liquid paraffin.

Diprosone Lotion (0.05% w/w): Each mL contains betamethasone dipropionate equivalent to betamethasone 0.47 mg in a vehicle consisting of isopropyl alcohol, carbomer 934P, sodium hydroxide and purified water.

PHARMACOLOGY

Betamethasone dipropionate is a potent topically-active corticosteroid producing prompt, marked and prolonged anti-inflammatory, anti-pruritic and vasoconstrictive effects.

According to the McKenzie-Stoughton Vasoconstrictor Test, betamethasone dipropionate was demonstrated to be significantly more active ($p<0.05$) than betamethasone valerate, fluocortolone, and flumethasone pivalate. While the direct applicability of this vasoconstrictor test to clinical situations has not been demonstrated conclusively, the results showed betamethasone dipropionate to be active in a concentration of 0.000016%, the lowest concentration tested which showed activity.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of the epidermal barrier and the use of occlusive dressings.

While topical corticosteroids can be absorbed from normal intact skin, dermal inflammation and/or other dermatologic disease processed may increase percutaneous absorption. Occlusive dressings also substantially increase percutaneous absorption.

After dermal absorption, topical corticosteroids enter pharmacokinetic pathways similar to those of systemically administered corticosteroids. In varying degrees, corticosteroids are bound to plasma proteins. They are metabolised primarily in the liver and excreted by the kidneys. Some topical corticosteroids and their metabolites undergo biliary excretion.

INDICATIONS

Diprosone is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. These include atopic eczema, infantile eczema, nummular eczema, contact dermatitis, neurodermatitis, anogenital and senile pruritus, lichen planus, intertrigo and psoriasis.
Diprosone Lotion is indicated wherever hair impedes access to the skin in the treatment of corticosteroid-responsive dermatoses particularly on the scalp, chest and underarms, etc. It is also indicated in the treatment of seborrhoea and psoriasis of the scalp.

CONTRAINDICATIONS

Hypersensitivity to betamethasone dipropionate, other corticosteroids or any components in Diprosone. Like other topical corticosteroids, Diprosone preparations are contraindicated in most viral infections of the skin, such as vaccinia, varicella, Herpes simplex, and also tuberculosis and acne rosacea.

PRECAUTIONS

Diprosone preparations should not be used in or near the eyes.

If irritation or sensitisation develops, treatment should be discontinued and appropriate therapy instituted.

In the presence of an infection, an appropriate antifungal or antibacterial agent should be administered. If a favourable response does not occur promptly, Diprosone should be discontinued until the infection has been controlled adequately.

Corticosteroids are known to be absorbed percutaneously, therefore in patients under prolonged and extensive topical treatment, the possibility of systemic effects should be kept in mind. This applies particularly when using the occlusive dressing technique.

Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Patients applying large doses of potent topical corticosteroids over large body surface areas should be evaluated periodically for evidence of HPA axis suppression. Patients applying doses of Diprosone in excess of 15g per day should be carefully monitored.

Suitable precautions should be taken when using topical corticosteroids in patients with st .s dermatitis and other skin diseases with impaired circulation.

Topical corticosteroid preparations may produce striae or atrophy of the skin or subcutaneous tissue. If this occurs, treatment should be discontinued.

In most cases, 4 weeks continuous treatment should be considered the maximum.

Use in Children

Chronic corticosteroid therapy may interfere with the growth and development of children. Paediatric patients may demonstrate greater susceptibility than mature patients to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects because of greater absorption due to a larger skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilaterial papilloedema.

Use in Pregnancy (Category A)

Topical corticosteroids should not be used extensively on pregnant patients in large amounts or for prolonged periods of time.

Use in lactation

Due to lack of data on the safety of betamethasone dipropionate in lactation, care should be exercised to ensure that the potential benefits to the lactating mother outweigh the possible hazards to the nursing infant.

ADVERSE REACTIONS

The following adverse reactions have been reported with the use of topical corticosteroids: itching, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

Rarely reported adverse effects include tingling, prickly skin/tightening or cracking of skin, warm feeling, laminar scaling and perilesional scaling, follicular rash, skin atrophy, erythema and telangiectasia.

DOSAGE AND ADMINISTRATION

Diprosone Cream, Ointment: Apply a small amount to the affected area twice daily. For some patients adequate maintenance therapy may be achieved with once daily application.

Diprosone Lotion: Apply twice daily. Part the hair with a comb, then apply with nozzle directly on the scalp. Squeeze bottle gently.

In most cases, 4 weeks continuous treatment should be considered the maximum.

Children: Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen.

OVERDOSAGE

Symptoms: Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal function resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism, including Cushing's disease.

Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

PRESENTATION

Diprosone Cream, Ointment 0.05% w/w (0.5 mg/g): 15 g and 50g tubes.
Diprosone Lotion 0.05% w/w (0.47 mg/mL): 30 mL bottles.

STORAGE

Diprosone Cream, Ointment, Lotion: Store below ~~30~~25°C.

POISONS SCHEDULES

S4

SPONSOR

Schering-Plough Pty LTD
~~11 GIBBON ROAD~~
~~BAULKHAM HILLS NSW 2153~~
Level 4, 66 Waterloo Road
North Ryde, NSW 2113
Australia

This Product Information was approved by the Therapeutic Goods Administration on 3 May 1996.

Date of most recent amendment: 22 February 2008.

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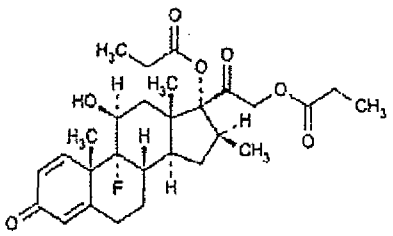

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