

NEW ZEALAND DATA SHEET

DIPROSONE CREAM AND OINTMENT

Name of Medicine

DIPROSONE

Betamethasone dipropionate equivalent to betamethasone 0.5mg/g (0.05% w/w) cream and ointment.

Presentation

DIPROSONE Cream is a white cream containing betamethasone dipropionate equivalent to betamethasone 0.5mg/g in a paraben-free water-washable vanishing cream base containing chlorocresol 1mg/g as preservative, soft white paraffin, liquid paraffin, cetostearyl alcohol, cetomacrogol 1000, sodium phosphate monobasic dihydrate, phosphoric acid and purified water.

DIPROSONE Ointment is an off-white ointment containing betamethasone dipropionate equivalent to betamethasone 0.5mg/g in a preservative-free ointment base containing soft white paraffin and liquid paraffin.

Uses

Action

Betamethasone dipropionate is a potent topically active corticosteroid producing prompt and marked 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 dermatological disease processes 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 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.

Dosage and Administration

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

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.

Contraindications

Hypersensitivity to betamethasone dipropionate, other corticosteroids or any of the components. Like other topical corticosteroids, DIPROSONE preparations are contraindicated in viral infections of the skin, such as vaccinia, varicella and Herpes simplex, also tuberculosis, acne rosacea, fungal skin infections (moniliasis), perioral dermatitis and ulcerative conditions.

Warnings and 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 within a few days to a week, 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. 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 stasis dermatitis and other skin diseases with impaired circulation.

Prolonged use on flexures and intertriginous areas is undesirable.

Topical corticosteroid preparations may produce striae or atrophy of the skin or subcutaneous tissue. If this occurs, treatment should be discontinued. In most cases, four weeks continuous treatment should be considered the maximum.

Use in Children

Chronic corticosteroid therapy may interfere with the growth and development of children. Babies and children up to four years should not be treated with topical steroids for longer than three weeks. In infants the napkins may act as an occlusive dressing and increase absorption.

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects than mature patients 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 bilateral papilloedema.

Use in Pregnancy

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 Effects

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 skin, secondary infection, striae and miliaria.

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

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 hypercorticotoid symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic corticosteroid toxicity, slow withdrawal of steroids is advised.

Pharmaceutical Precautions

Store below 25°C

MEDICINE CLASSIFICATION

Prescription medicine

PACKAGE QUANTITIES

Cream and Ointment: 15 g and 50 g tubes

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