Important information. Please read carefully.

Uniqler

Cream 0.05% w/w

COMPOSITION

Contains 0.05% w/w Betamethasone (as Betamethasone Dipropionate).
Chlorocresol 0.15% w/w as preservative.

PHARMACODYNAMICS

Diprosone preparations contain the dipropionate ester of betamethasone which is a glucocorticoid exhibiting the general properties of corticosteroids.

In pharmacological doses, corticosteroids are used primarily for their anti-inflammatory and/or immune suppressive effects.

Topical corticosteroids such as betamethasone dipropionate are effective in the treatment of a range of dermatoses because of their anti-inflammatory, anti-pruritic and vasoconstrictive actions. However, while the physiologic, pharmacologic and clinical effects of the corticosteroids are well known, the exact mechanisms of their action in each disease are uncertain.

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.

Topical corticosteroids can be absorbed through intact, normal skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees, are metabolised primarily in the liver and excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

INDICATIONS

Uniqler Cream is indicated for the relief of the inflammatory manifestations of corticosteroid-responsive dermatoses such as: psoriasis, contact dermatitis (dermatitis venenata), atopic dermatitis (infantile eczema, allergic dermatitis), neurodermatitis (lichen simplex chronicus), lichen palnus, eczema (including nummular eczema, hand eczema,

eczematous dermatitis), intertrigo, dyshidrosis (pompholyx), seborrheic dermatitis, exfoliative dermatitis, solar dermatitis, stasis dermatitis and anogenital and senile pruritus.

DOSAGE AND ADMINISTRATION
Apply a thin film to the affected skin areas once or twice daily as directed by your doctor or pharmacist.

CONTRAINDICATIONS
It is contraindicated in patients with a history of sensitivity to betamethasone dipropionate, other corticosteroids or to any of the components in these preparations.

WARNINGS AND PRECAUTIONS
Systemic absorption of topical corticosteroids can produce reversible Hypothalamic-Pituitary-Adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome also can be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients receiving a large dose of potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

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

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation or sensitization develops, treatment should be discontinued an appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroids should be discontinued until the infection has been controlled adequately.

This product is not for ophthalmic use.

Local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. If used in children or on the face courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age.

Occlusion must not be used.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons, including rebound relapses following development of tolerance, risk of generalised pustular psoriasis and local systemic toxicity due to impaired barrier function of the skin. Careful patient supervision is important.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) 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 of visual disturbances 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.

DRUG INTERACTIONS
No known data.

PREGNANCY AND LACTATION
Pregnancy
There are no adequate and well controlled studies of the teratogenic potential of topically applied corticosteroids in pregnant woman. Therefore, topical steroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation:
It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in breast milk. Caution should be exercised when this product is administered to nursing mothers.

SIDE EFFECTS
The following local adverse reactions have been reported with the use of betamethasone dipropionate cream which include burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE
Excessive prolonged use of topical steroids can suppress hypothalamic-pituitary adrenal function resulting in adrenal insufficiency. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, reduce the frequency of application, or to substitute with a less potent steroid.

STORAGE CONDITION
Store below 30°C.

SHELF LIFE
The expiry date is indicated on the packaging.

PRODUCT DESCRIPTION, DOSAGE FORM AND PACKAGING AVAILABLE
White, smooth, homogeneous cream.
Available in pack size of 15g.

For further information, please consult your physician or pharmacist.
Revision Date: 30-Jul-2021

Manufacturer and Product Registration Holder
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