

DERMOL SCALP APPLICATION

Clobetasol propionate 0.05% w/w



DATA SHEET

Presentation

DERMOL Scalp Application is an almost clear, colourless liquid containing 0.05% w/w clobetasol propionate.

Uses

Actions

Clobetasol propionate is a highly-active corticosteroid with topical anti-inflammatory activity. The major effect of clobetasol propionate on skin is a non-specific anti-inflammatory response partially due to vasoconstriction and decrease in collagen synthesis.

Pharmacokinetics

Percutaneous penetration of clobetasol propionate varies among individuals and can be increased by the use of occlusive dressings, or when the skin is inflamed or diseased.

Following percutaneous absorption of clobetasol propionate the drug follows the metabolic pathway of systemically administered corticosteroids, i.e. metabolised primarily by the liver and then excreted by the kidneys. However, systemic metabolism of clobetasol has never been fully characterised or quantified.

Indications

Treatment of psoriasis and recalcitrant eczemas of the scalp.

Dosage and Administration

Apply sparingly to the scalp night and morning until improvement occurs. As with other highly-active topical steroid preparations, therapy should be discontinued when control is achieved. Repeated short courses of DERMOL Scalp Application may be used to control exacerbations. If continuous steroid treatment is necessary, a less potent preparation should be used.

Contraindications

Infections of the scalp.

Hypersensitivity to the preparation.

Dermatoses in children under one year of age, including dermatitis.

Warnings and Precautions

Care must be taken to keep the preparation away from the eyes. Do not use near a naked flame.

Long-term continuous topical therapy should be avoided, particularly in infants and children, as adrenal suppression can occur readily even without occlusion.

Development of secondary infection requires withdrawal of topical corticosteroid therapy and commencement of appropriate systemic antimicrobial therapy.

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

The least potent corticosteroid which will control the disease should be selected.

Pregnancy and Lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development, including cleft palate and intrauterine growth retardation. The relevance of this finding to human beings has not been established; therefore, topical steroids should not be used extensively in pregnancy, ie. in large amounts or for prolonged periods

The safe use of clobetasol propionate during lactation has not been established.

Adverse Effects

The following adverse reactions have been identified during post-approval use of clobetasol propionate. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The frequency of these adverse events has therefore been classified as "unknown".

Immune system disorders

Hypersensitivity

Local hypersensitivity reactions such as erythema, rash, pruritus, urticaria and allergic contact dermatitis may occur at the site of application and may resemble symptoms of the condition under treatment.

If signs of hypersensitivity appear, application should be stopped immediately.

Endocrine disorders

Features of Cushing's syndrome

As with other topical corticosteroids, prolonged use of large amounts or treatment of extensive areas can result in sufficient systemic absorption to produce the features of Cushing's syndrome. This effect is more likely to occur in infants and children, and if occlusive dressings are used.

Skin and subcutaneous tissue disorders

Local skin burning, local atrophy, pustular psoriasis.

Local atrophy may occur after prolonged treatment.

Treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.

Interactions

None known.

Overdosage

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse, the features of hypercortisolism may appear and in this situation topical steroids should be reduced or discontinued gradually, under medical supervision.

Pharmaceutical Precautions

Store below 25°C.

Medicine Classification

Prescription Medicine.

Package Quantities

Plastic squeeze bottle with elongated nozzle containing 30 mL.

Further Information

DERMOL Scalp Application also contains isopropyl alcohol, sodium hydroxide, carbomer 934P, and purified water.

Name and Address

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