

# NEW ZEALAND DATA SHEET

## DERMOL

*Clobetasol propionate 0.05% w/w Cream and Ointment*



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## Presentation

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DERMOL Cream and Ointment each contain 0.05% w/w clobetasol propionate. The water-miscible cream and the paraffin-based ointment are both white in appearance.

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## Uses

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### *Actions*

Clobetasol propionate is a highly active corticosteroid with topical anti-inflammatory activity, which is of particular value when used in short courses for conditions which do not respond satisfactorily to less active corticosteroids. 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.

Mean peak plasma clobetasol propionate concentrations of 0.63ng/mL occurred in one study eight hours after the second application (13 hours after an initial application) of 30g clobetasol propionate 0.05% ointment to normal individuals with healthy skin. Following the application of a second dose of 30g clobetasol propionate cream 0.05% mean peak plasma concentrations were slightly higher than the ointment and occurred 10 hours after application.

In a separate study, mean peak plasma concentrations of approximately 2.3ng/mL and 4.6ng/mL occurred respectively in patients with psoriasis and eczema three hours after single application of 25g clobetasol propionate 0.05% ointment.

Following percutaneous absorption of clobetasol propionate the drug probably 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 resistant dermatoses such as psoriasis (excluding widespread plaque psoriasis), recalcitrant eczemas, lichen planus and discoid lupus erythematosus and other skin conditions which do not respond satisfactorily to less active steroids.

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## Dosage and Administration

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Apply sparingly to the affected area once or twice daily until improvement occurs. As with other highly active topical steroid preparations, therapy should be discontinued when control is achieved. In the more responsive conditions this may be within a few days.

If no improvement is seen within two to four weeks, reassessment of the diagnosis, or referral, may be necessary.

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Repeated short courses of DERMOL Cream or Ointment may be used to control exacerbations. If continuous steroid treatment is necessary, a less potent preparation should be used.

In very resistant lesions, especially where there is hyperkeratosis, the anti-inflammatory effect of DERMOL Cream or Ointment can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response. Thereafter improvement can usually be maintained by application without occlusion.

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## Contraindications

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Rosacea, acne vulgaris and perioral dermatitis. Primary cutaneous viral infections (e.g. herpes simplex, chickenpox).

Hypersensitivity to the preparation.

The use of DERMOL Cream or Ointment is not indicated in the treatment of primary infected skin lesions caused by infection with fungi (e.g. candidiasis, tinea), or bacteria (e.g. impetigo), perianal and genital pruritus, or dermatoses in children under one year of age, including dermatitis and napkin eruptions.

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## Warnings and Precautions

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

If used in childhood or on the face, courses should be limited if possible to five days and occlusion should not be used. It should be noted that the infant's napkin may act as an occlusive dressing.

The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema.

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If DERMOL Cream or Ointment enter the eye, the affected eye should be bathed in copious amounts of water.

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.

Appropriate anti-microbial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic administration of anti-microbial agents. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and so the skin should be cleansed before a fresh dressing is applied.

The least potent corticosteroid which will control the disease should be selected. Patients should be advised to wash their hands after applying DERMOL Cream or Ointment unless it is the hands that are being treated.

### ***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 humans has not been established, therefore, topical corticosteroids should not be used extensively in pregnancy, i.e., in large amounts or for prolonged periods

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

### ***Effects on ability to drive and use machines***

Clobetasol propionate is not expected to have any effects.

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## Adverse Effects

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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. In infants, the nappy may act as an occlusive dressing..

Provided the weekly dosage is less than 50 g in adults, any suppression of the HPA axis is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased. The same applies to children given proportionate dosage.

### ***Vascular disorders***

Dilatation of the superficial blood vessels.

Prolonged and intensive treatment with highly-active corticosteroid preparations may cause dilatation of the superficial blood vessels, particularly when occlusive dressings are used or when skin folds are involved.

### ***Skin and subcutaneous tissue disorders***

Local skin burning, local atrophy, striae, thinning, pigmentation changes, hypertrichosis, exacerbation of underlying symptoms, pustular psoriasis.

Prolonged and intensive treatment with highly-active corticosteroid preparations may cause local atrophic changes, such as thinning and striae.

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

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## Interactions

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None reported.

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## Overdosage

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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 corticosteroids should be reduced or discontinued gradually under medical supervision.

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## Pharmaceutical Precautions

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Store below 25°C, out of direct sunlight.

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## Medicine Classification

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Prescription Medicine.

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## Package Quantities

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Tubes of 30 g.

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## Further Information

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DERMOL Cream and Ointment each contain 0.05% w/w clobetasol propionate.

DERMOL Cream also contains propylene glycol, glycerol monostearate, glyceryl stearate/ PEG stearate, cetostearyl alcohol, white beeswax, citric acid anhydrous, chlorocresol, sodium citrate dihydrate and purified water.

DERMOL Ointment also contains white soft paraffin, propylene glycol and sorbitan sesquioleate.

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## Name and Address

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## Date of Preparation

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7 July 2010

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