Dermovate™ Ointment

Clobetasol Propionate

To the Medical and Pharmaceutical Professions.

Presentation

Clobetasol 17-propionate 0.05375% w/w

Indications

Clobetasol propionate is a very active topical corticosteroid which is of particular value when used in short courses for the treatment of more resistant dermatoses such as:

Psoriasis (excluding widespread plaque psoriasis).

Recalcitrant eczemas.

Lichen planus.

Discoid lupus erythematosus and other skin conditions which do not respond satisfactorily to less active steroids.

Dosage and Administration

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. Repeated short courses of *DERMOVATE* 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 *DERMOVATE* 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.

For topical administration.

Contraindications

Hypersensitivity to the preparation.

Rosacea.

Acne vulgaris.

Perioral dermatitis.

Perianal and genital pruritus.

Primary cutaneous viral infections (e.g., herpes simplex, chickenpox).

The use of *DERMOVATE* skin preparations is not indicated in the treatment of primary infected skin lesions caused by infection with fungi or bacteria; dermatoses in children under one year of age, including dermatitis and napkin eruptions.

Warnings and Precautions

Topical steroids 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 antimicrobial 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 antimicrobial agents.

Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and the skin should be cleansed before a fresh dressing is applied.

Long-term continuous therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur even without occlusion. If *DERMOVATE* is required for use in children, it is recommended that the treatment should be reviewed weekly. It should be noted that the infant's napkin may act as an occlusive dressing.

If used in childhood or on the face, courses should be limited if possible to five days and occlusion should not be used.

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.

Interactions.

None Reported.

Pregnancy and Lactation

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established, however, topical steroids should not be used extensively in pregnancy, i.e., in large amounts for prolonged periods.

The safe use of *DERMOVATE* during lactation has not been established.

Effects on Ability to Drive and Use Machinery

DERMOVATE is not expected to have any effect.

Adverse Reactions

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10,000 and, <1/1000) and very rare (≤1/10,000) including isolated reports. Very common, common and uncommon events were generally determined from clinical trial data. The background rates in placebo and comparator groups were not taken into account when assigning frequency categories to adverse events derived from clinical trial data, since these rates were generally comparable to those in the active treatment group. Rare and very rare events were generally determined from spontaneous data.

Immune system disorders

Very rare: Hypersensitivity

Local hypersensitivity reactions such as erythema, rash, pruritus, urticaria, local skin burning 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

Very rare: Features of Hypercortisolism

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 hypercortisolism. This effect is more likely to occur in infants and children, and if occlusive dressings are used. In infants, the napkin 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.

Vascular disorders

Uncommon: 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

Uncommon: Local atrophy, striae

Very rare: 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, particularly when occlusive dressings are used, or when skin folds are involved.

In very rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.

Overdose

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

Pharmacological Properties

Pharmacodynamics

The major effect of clobetasol propionate on skin is a non-specific anti-inflammatory response, as a result of vasoconstriction and decrease in collagen synthesis.

Pharmacokinetics

Absorption

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.

Distribution

Mean peak plasma clobetasol propionate concentrations of 0.63 ng/ml occurred in one study eight hours after the second application (13 hours after an initial application) of 30 g clobetasol propionate 0.05 % ointment to normal individuals with healthy skin. Following the application of a second dose of 30 g 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 2.3 ng/ml and 4.6 ng/ml occurred respectively in patients with psoriasis and eczema three hours after a single application of 25 g clobetasol propionate 0.05 % ointment.

Metabolism

Following percutaneous absorption of clobetasol propionate the drug probably follows the metabolic pathway of systemically administered corticosteroids. However, systemic metabolism of clobetasol has never been fully characterised or quantified.

Pharmaceutical Particulars

List of Excipients

Propylene glycol

Sorbitan sesquioleate

White soft paraffin

Shelf Life

The expiry date is indicated on the outer packaging.

Special Precautions for Storage

Store below 30°C.

Instructions for Use/Handling

Patients should be advised to wash their hands after applying *DERMOVATE* , unless it is the hands that are being treated.

Manufactured by Glaxo Operations UK Limited*,
Barnard Castle, UK
*Member of the GlaxoSmithKline group of companies

Date of text update: GDS v09 - 13 September 2006

THIS IS A MEDICAMENT

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.

GlaxoSmithKline