

Topiclo[®]

0.05% w/w
Clobetasol Propionate USP Cream and Ointment

DESCRIPTION

Topiclo[®] cream/ointment contains 0.05% w/w Clobetasol Propionate, Clobetasol Propionate is a very active topical corticosteroid, which is of particular value when used in short courses for conditions which do not respond satisfactorily to less active steroids.

INDICATIONS

Topiclo[®] is indicated for the 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.

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. In very resistant lesions, especially where there is hyperkeratosis, the anti-inflammatory effect of Clobetasol Propionate 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.

SIDE EFFECTS

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 hypercorticism.

Prolonged and intensive treatment with a highly active corticosteroid preparation may cause local atrophic changes in the skin such as thinning, striae and dilatation of the superficial blood vessels, particularly when occlusive dressings are used or when skin folds are involved.

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

There are reports of pigmentation changes and hypertrichosis with topical steroids. Clobetasol Propionate is usually well tolerated, but if signs of hypersensitivity appear, application should be stopped immediately. Exacerbation of symptoms may occur.

USE IN 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 deformed palate and intrauterine growth retardation. 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. There may be a very small risk of abnormal foetal development in the human foetus.

CONTRAINDICATIONS

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

Hypersensitivity to the preparation.

The use of Clobetasol Propionate skin preparations is not indicated in the treatment of primarily infected skin lesions caused by infection with fungi (e.g. candidiasis, tinea), or bacteria (e.g. impetigo); perianal and genital pruritus.

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

PRECAUTIONS

Long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur readily 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.

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 eye lids, care is needed to ensure that the preparation does not enter the eye, as glaucoma or cataract might result.

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.

PHARMACEUTICAL PRECAUTIONS

Keep away from light and wet place. Store below 15 °C - 25 °C temperature . Do not store at refrigerator. Keep out of reach of children.

PACKAGING

Topiclo[®] cream/ointment: Each gram cream/ointment contains Clobetasol Propionate USP 0.50 mg.

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Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

GAZIPUR, BANGLADESH

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