Axcel®

CLOBETASOL 0.05%

AXCEL CLOBETASOL 0.05% CREAM

COMPOSITION:
Clobetasol Propionate 0.05% w/w
Chlorocresol 0.1% w/w as preservative

PRESENTATION:
White to off white coloured, water miscible cream.

AXCEL CLOBETASOL 0.05% OINTMENT

COMPOSITION:
Clobetasol Propionate 0.05% w/w

PRESENTATION:
Translucent, waxy, water immiscible ointment.

INDICATIONS:
Clobetasol Propionate is a potent topical corticosteroid indicated for short courses treatment of more resistant dermatoses such as psoriasis (excluding widespread plaque psoriasis), recalcitrant eczemas, lichen planus, discoid lupus erythematosus, and other conditions which do not respond satisfactorily to less active steroids.

PHARMACOLOGY:
Mechanism of Action:
Clobetasol propionate is a highly active corticosteroid. It is effective in the treatment of corticosteroids-responsive dermatoses because of their anti-inflammatory, antipruritic and vasoconstrictive actions. However, the exact mechanisms of their action in each disease are uncertain. Corticosteroids are absorbed from sites of topical application. When applied topically, particularly to large areas, when the skin is broken, or under occlusive dressings, sufficient corticosteroid may be absorbed to give systemic effects. Most corticosteroids in the circulation are bound to plasma protein. The corticosteroid-binding globulin has high affinity but low binding capacity, while the albumin has low affinity but large binding capacity. The synthetic corticosteroids are less extensively protein bound than natural corticosteroids. Corticosteroids are metabolized mainly in the liver but also in the kidney and are excreted in the urine. The slow metabolism of the synthetic corticosteroids with the lower protein-binding affinity may account for their increased potency compare with the nature corticosteroids.

DIRECTIONS FOR USE:
Apply sparingly to the affected area once or twice daily until improvement occurs; normally within a few days in the more responsive conditions. Discontinue the therapy when control is achieved. If a longer course is required, it is recommended that treatment should not be continued for more than 4 weeks without the patient's condition being reviewed. Repeated short courses of the Clobetasol Propionate may be used to control exacerbations. A less potent preparation should be used if continuous steroid treatment is necessary. In vary resistant lesions, especially where there is hyperkeratosis, the anti-inflammatory effect of Clobetasol Propionate can be enhanced by occluding the treatment area with polythene film. Overnight occlusion is usually adequate to bring about satisfactory response. Thereafter improvement can usually be maintained by application without occlusion.

CONTRAINDICATIONS:
Dermatoses in children under 1 year of age, including dermatitis and napkin eruptions. Rosacea, acne vulgaris and perioral dermatitis. Perianal and genital pruritus. Primary cutaneous viral infection (e.g. herpes simplex, chicken pox). It is not indicated for the treatment of primarily infected skin lesions caused by fungi or bacteria infection. Hypersensitivity to the preparation.

PRECAUTION:
Systemic absorption of topical corticosteroids should always be considered. It should not be applied with an occlusive dressing to large areas of the body. Long-term continuous topical therapy should be avoided, especially in children. If Clobetasol Propionate is required for use in children, it is recommended that the treatment should be reviewed weekly, so that the least potent corticosteroid that will control the disease can be selected. It should be noted that, the infant's napkin might 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. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eyes as might cause corneal ulcers, raised intra-ocular pressure and reduced visual function. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic administration of appropriate antimicrobial product. Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalized pustular psoriasis and development of local and systemic toxicity due to impair barrier function of the skin. If used in psoriasis careful patient supervision is important.

Use in Pregnancy & Lactation:
There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can caused 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, such as in large amounts or for prolonged periods. The safe use of topical corticosteroids during lactation has not been established.

SIDE EFFECTS:
When administration of topical corticosteroids is prolonged, when the site of the application is covered with an occlusive dressing, or when large areas of the skin are involved, the absorption may result in sufficient systemic absorption to produce the features of hypercorticism. This effect is more likely to occur in infants and children, and if occlusive dressing are used. In Infants, the napkin may act as an occlusive dressing. Hypersensitivity reactions and exacerbation of symptoms may occur. Provided the weekly dosage is not exceed 50g in adults, any pituitary-adrenal suppression 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. Prolong and intensive treatment with potent topical corticosteroid preparations may cause atrophic change such as striae, thinning of the skin and dilatation of the superficial blood vessels, particularly when occlusive dressings are used, or when the 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. Axcel Clobetasol is usually well tolerated, but if signs of hypersensitivity appear, application should be stopped immediately. There are reports of pigmentation changes and hypertrichosis with topical steroids.

OVERDOSAGE AND TREATMENT :
Acute overdosage is unlikely to occur, however, in case of chronic overdosage or misuse the features of hypercorticism may appear and topical corticosteroids should be discontinued.

STORAGE:
Store below 30°C. Protect from light.

PACK QUANTITIES:
Available in 5g and 15g in aluminium tube.

Further information can be obtained from pharmacist, physician or the manufacturer.

AXCEL CLOBETASOL 0.05% CREAM - MAL08010740AZ
AXCEL CLOBETASOL 0.05% OINTMENT - MAL07124643AZ

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