

DYNA CLOBETASOL CREAM 0.05%

MAL19961875AZ

DESCRIPTION:

CREAM

Colour : White
Fragrance : Natural

CONTENT:

Clobetasol Propionate 0.05% w/w
Preservative: Chlorocresol 0.1% w/w

PHARMACODYNAMICS:

Corticosteroids diffuse across cell membranes and complex with specific cytoplasmic receptors. These complexes then enter the cell nucleus, bind to DNA and stimulate transcription of messenger RNA (mRNA) and subsequent protein synthesis of various enzymes thought to be ultimately responsible for anti-inflammatory effects to topical application of corticosteroid.

PHARMACOKINETICS:

Corticosteroids when applied topically, particularly under an occlusive dressing or when the skin is broken, sufficient corticosteroid may be absorbed to give systemic effects. Corticosteroids in the circulation are extensively bound to plasma proteins, mainly to globulin and less so to albumin. The corticosteroid-binding globulin has high affinity but low binding capacity, which the albumin has low affinity but large binding capacity. Only unbound corticosteroid has pharmacological effects or is metabolised. The synthetic corticosteroids are less extensively protein bound than hydrocortisone (cortisol). They also tend to have longer half-lives. Corticosteroids are metabolised mainly in the liver but also in the kidney, and are excreted in the urine. The slower metabolism of the synthetic corticosteroids with their lower protein-binding affinity may account for their increased potency compared with the natural corticosteroids.

INDICATIONS:

Treatment of more resistant dermatoses, eg psoriasis, recalcitrant eczemas, lichen planus, discoid lupus erythematosus and other conditions which do not respond satisfactorily to less active steroids.

RECOMMENDED DOSE:

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 a longer course is necessary, it is recommended that treatment should not be continued for more than 4 weeks without the patients condition being reviewed.

CONTRAINDICATIONS:

Rosacea, acne vulgaris and perioral dermatitis. Dermatitis in children under 1 year, including dermatitis and napkin eruptions. Skin lesions caused by infection with viruses (eg, herpes simplex, chickenpox), fungi (eg, candidiasis, tinea) or bacteria (eg, impetigo). Hypersensitivity to the preparation.

WARNING AND PRECAUTIONS:

Long term continuous therapy with corticosteroid preparations should be avoided, particularly in infants and children, in whom adrenal suppression occurs readily. If corticosteroid preparations are required for use in children, it is recommended that the treatment should be reviewed weekly. 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 eye, as glaucoma might result. 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.

PREGNANCY AND LACTATION:

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of growth retardation. There may therefore be a very small risk of such effects in the human fetus.

SIDE EFFECTS/ADVERSE REACTIONS:

Prolonged and intensive treatment with highly active corticosteroid preparations may cause atrophic changes, eg. striae, thinning of the skin and dilatation of the superficial blood vessels, particularly when occlusive dressings are used, or where 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. Prolonged use of large amounts or treatment of extensive areas can result in sufficient systemic absorption to produce the features of hypercorticism. Use of occlusive dressing increases the absorption of topical corticosteroids. In infants, the napkin may act as occlusive dressing.

SYMPTOMS AND TREATMENT OF OVERDOSE:

For topical application of corticosteroids, problems of overdosage are unlikely to be encountered. For chronic topical overdose, treatment is symptomatic, supportive, and consists of discontinuance of topical adrenocorticoid therapy. Gradual withdrawal of the preparation may be necessary. Consult the doctor immediately if any unusual serious reactions happened.

PACKING/PACK SIZE(S):

Aluminium tube of 15 g and 50x15 g.

**JAUHI UBAT DARIPADA KANAK-KANAK
KEEP OUT OF REACH OF CHILDREN
FOR EXTERNAL USE ONLY**

MANUFACTURER/PRODUCT REGISTRATION HOLDER:

DYNAPHARM (M) SDN. BHD. (65683-V)
2497, Mk. 1, Lorong Perusahaan Baru 5,
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