

ClobeonTM Clobetasol Propionate, Neomycin Sulfate & Nystatin

Composition:

ClobeonTM Cream: Each gram cream contains Clobetasol Propionate BP 0.5 mg, Neomycin Sulfate USP 5 mg & Nystatin USP 100,000 units.

Description:

ClobeonTM Cream is a combination of topical preparation of a potent corticosteroid, Clobetasol Propionate, an aminoglycoside anti-bacterial, which has both anti-inflammatory & immunosuppressive properties, Neomycin Sulfate & an anti-fungal agent Nystatin. Corticosteroids are supposed to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2. Neomycin binds to the ribosomal 30s & 50s subunits of susceptible bacteria & inhibits protein synthesis. Neomycin also causes the misreading of the genetic codes of the mRNA template & this causes incorrect amino acids to be incorporated into the growing polypeptide chain. On the other hand, Nystatin binds with ergosterol in plasma membrane of fungal cells, resulting the formation of pores, which disrupt membrane functions & allowing electrolytes particularly potassium & small molecules to leak out from the cell, resulting in cell death.

Indications:

ClobeonTM Cream is indicated for the treatment of inflamed skin conditions such as eczema, psoriasis & dermatitis, which do not respond to weaker steroid treatments. In addition it can help to prevent or clean up some bacterial & fungal infections that can make such conditions worse.

Dosage & Administration:

Adults and children over 2 years:

Apply thinly to the affected area once or twice daily until improvement occurs. In very resistant lesions, especially where there is hyperkeratosis, the anti-inflammatory effect of **ClobeonTM** can be enhanced, if necessary, occlusive dressing (with polythene) should be used. Treatment should not be continued for more than 7 days without medical supervision. If a longer course is necessary, 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 **ClobeonTM** may be used to control exacerbations. If continuous steroid treatment is necessary, a less potent preparation should be used.

Children: **ClobeonTM** is suitable for use in children aged 2 years and over at the same dose as adults. This drug is not recommended for use in neonates and infants less than 2 years of age.

OR AS DIRECTED BY THE PHYSICIAN.

Side Effects:

Local hypersensitivity reactions such as erythema, rash, pruritus, urticaria, local skin burning and allergic contact dermatitis may occur at the site of application. Hypercortisolism especially in infants & children if occlusive dressings are used, local atrophic changes in the skin such as thinning and dilatation of the superficial blood vessels, reports of pigmentation changes and hypertrichosis, exacerbation of symptoms may occur.

Precautions:

Long-term continuous topical therapy should be avoided where possible, particularly in infants and children. If used in childhood, or on the face, courses should be limited to 5 days and occlusion should not be used. It should be noted that the child's napkin may act as an occlusive dressing. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If this preparation does 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 generalized 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. 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.

Pregnancy: Not recommended.

Lactation: Not recommended.

Renal Impairment: Dosage should be reduced in patients with reduced renal function.

Contraindications:

This preparation is contraindicated in patients with Rosacea, acne vulgaris & perioral dermatitis, primary cutaneous viral infections, hypersensitivity to the preparations. Use of this preparation is not indicated in the treatment of primary infected skin lesions caused by infection with fungi, bacteria or yeast, secondary infections due to *Pseudomonas* or *Proteus* species, perianal & genital pruritus, dermatoses in children under 2 years of age, including dermatitis & napkin eruptions. Preparations containing Neomycin should not be used for the treatment of otitis externa when the ear drum is perforated, because of the risk of ototoxicity. A possibility of increased absorption exists in very young children, therefore it is not recommended for use in neonates & infants (up to 2 years).

Storage Condition:

Keep below 30^o C. Keep out of the reach of children.

Presentation:

Clobeon™ Cream: Each tube contains 10 g of cream.