CLONATE NN Cream

Clobetasol Propionate BP, Neomycin Sulphate BP & Nystatin BP

Composition:

Each gram Clonate NN cream contains Clobetasol Propionate BP 0.5 mg, Neomycin Sulphate BP 5 mg and Nystatin BP 100,000 units.

Description:

Clobetasol propionate is a very potent corticosteroid with topical anti-inflammatory activity. The mechanism of the topical steroids like Clobetasol, in general, is unclear. When clobetasol is applied to the skin it works by acting inside the skin cells to decrease the release of inflammatory substances which reduces swelling, redness and itch. The major effect of Clobetasol Propionate on skin is a non-specific anti-inflammatory response, partially due to vasoconstriction and decrease in collagen synthesis.

Neomycin Sulphate is a broad spectrum antibiotic of the aminoglycoside type and is used to treat bacterial infections. Neomycin binds to the ribosomal 30s and 50s sub-units of susceptible bacteria and inhibits protein synthesis that is necessary for survival. Neomycin also causes a misreading of the genetic codes of the mRNA template, causing incorrect amino acids to be incorporated into the growing polypeptide chain leading to production of abnormal and fatty proteins, ultimately resulting the killing of bacteria.

Nystatin is an antifungal agent that kills fungi and yeasts by interfering with their cell membranes. It works by binding with ergosterol, which is a component of fungal cell membranes with a resultant change in membrane permeability allowing leakage of essential intracellular components and fungal death.

Indications:

Clonate-NN Cream is indicated in:

- Short course treatment of recalcitrant eczemas
- Neurodermatoses
- Any inflammatory skin disorders (excluding widespread plaque psoriasis) where secondary bacterial or fungal infection is present, suspected or likely to occur
- Other inflammatory conditions which do not respond satisfactorily to less active steroids

Dosage and Administration:

Adults and children over 2 years:

Apply Clonate-NN cream sparingly to the affected area once or twice daily until the improvement occurs. The therapy should be discontinued when control is achieved. Treatment should not be continued for more than 7 days without medical supervision. It is recommended that the treatment should not be continued for more than 4 weeks without the patient's condition being reviewed. Repeated short courses of Clonate NN cream may be used to control exacerbations. In very resistant lesions, especially where there is hyperkeratosis, the anti-inflammatory effect of this preparation can be enhanced, if necessary, by occluding the treatment area with polythene.

Elderly: Clonate NN cream is suitable for use in the elderly patients. Caution should be exercised in cases where a decrease in renal function exists and significant systemic absorption of Neomycin Sulphate may occur.

Children: Clonate NN cream is suitable for use in children of 2 years and over at same dose as adults. A possibility of increased absorption exists in very young children, thus Clonate NN cream is not recommended for use in neonates and infants younger than 2 years.

Side-Effects:

Generally Clonate NN cream is well-tolerated.

As with other topical corticosteroids, prolonged use of large amount or treatment of extensive areas can result in sufficient systemic absorption to produce the features of hypercortisolism. The effect is more likely to occur in infants and children and if occlusive dressings are used.

However, a few side-effects after prolonged and intensive treatment 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. There are reports of pigmentation changes and hypertrichosis with topical steroids.

Contraindication:

This medication is contraindicated in patients with rosacea, acne vulgaris and perioral dermatitis, primary cutaneous viral infection e.g. *Herpes simplex,* chicken pox, cold sores, otitis externa with a perforated eardrum and who are hypersensitive to the preparation. This preparation is also contraindicated in children below 2 years of age.

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 to 5 days and occlusion should not be used. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye as glaucoma might result. If this medication enters into the eye, the affected eye should be thoroughly washed with copious amount of water. If used in psoriasis, careful patient supervision is important. If Clonate-NN cream is absorbed into the body in large amounts, the effects of medicines used to relax muscles during surgery can last longer or even be increased. Do not mix with any other creams or ointments.

Drug interaction:

Neomycin Sulphate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents following significant systemic absorption. However, if used in accordance with the recommendations, systemic exposure to Neomycin Sulphate is expected to be minimal and drug interactions are unlikely to be significant. No hazardous interactions have been reported with use of Clobetasol Propionate or Nystatin.

If patients need to use other topical medicines or moisturizers on the same area of skin, it is recommended that patients need to leave several minutes between applying each product.

If patient apply moisturizers shortly before or after applying this medicine, these can dilute the corticosteroid and potentially make it less effective. Try to apply moisturizers at a different time of day or at least 30 minutes before or after this one.

Overdose:

Acute overdosage is very unlikely to occur. No overdose related problem yet reported. However, in the case of chronic overdosage or misuse, the features of hypercortisolism may appear and the application should be discontinued gradually. Also, consideration should be given to significant systemic absorption of Neomycin Sulphate. If this is suspected, use of the product should be stopped and the patient's general status, hearing acuity, renal and neuromuscular functions should be monitored. Haemodialysis may reduce the serum level of Neomycin Sulphate.

Use in Pregnancy and Lactation:

Pregnancy Category C. The safety of this medicine during pregnancy and breastfeeding is not established. Neomycin present in the maternal blood can cross the placenta and may give rise to a theoretical risk of fetal toxicity, thus the use of the preparation is not recommended in pregnancy and lactation.

Storage condition:

Keep out of reach and sight of children. Keep in a cool and dry place.

How supplied:

Each aluminium collapsible tube contains 15 gm cream.

KEMIKO

Manufactured by :

KEMIKO PHARMACEUTICALS LTD.

Bangladesh