Dermex® NN

Clobetasol propionate + Neomycin + Nystatin

Description: Dermex® NN cream contains three active ingredients, Clobetasol propionate, Neomycin sulphate and Nystatin. Clobetasol propionate is a very potent corticosteroid. It is prescribed to treat severe inflammatory skin disorders such as eczema and psoriasis that have not responded to weaker corticosteroids. Neomycin sulphate is an antibiotic of the aminoglycoside type and is used to treat infections with bacteria. Nystatin is an antifungal that kills fungi and yeasts by interfering with their cell membranes.

Mode of action: The mechanism of action of the topical steroids like clobetasol, in general, is unclear. However, corticosteroids are thought to act by induction of phospholipase A_2 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. Neomycin binds to the ribosomal 30s and 50s sub-units of susceptible bacteria and inhibits protein synthesis. Neomycin also causes a misreading of the genetic codes of the mRNA template and this causes incorrect amino acids to be incorporated into the growing polypeptide chain. Nystatin acts by binding to sterols in the cell membrane of the fungus with a resultant change in membrane permeability allowing leakage of intracellular components.

Pharmacokinetics: Percutaneous penetration of clobetasol propionate varies among individuals and can be increased by the use of occlusive dressings, or when the skin is inflamed or diseased. Clobetasol propionate is bound to the plasma proteins in varying degrees. It is metabolized primarily in the liver and is excreted by the kidneys. Small amount of clobetasol propionate and its metabolite are also excreted into the bile. Absorption of neomycin has also been reported to occur from the peritoneum, respiratory tract, bladder, wounds, and inflamed skin. Once neomycin is absorbed it is rapidly excreted by the kidneys in active form. It has been reported to have a half-life of 2 to 3 hours.
Nystatin is poorly absorbed from the gastrointestinal tract. It is not absorbed through the skin or mucous membranes when applied topically.

Composition: Dermex® NN Cream: Each gram cream contains Clobetasol Propionate BP 0.5 mg, Neomycin Sulphate USP 5 mg and Nystatin BP 1,00,000 IU.

Indications: Clobetasol propionate is a highly active topical corticosteroid which is of particular value when used in short courses for the treatment of recalcitrant eczemas, neurodermatoses, and other conditions which do not respond satisfactorily to less active steroids.
Dermex® NN is indicated in more resistant dermatoses such as recalcitrant eczemas and psoriasis (excluding widespread plaque psoriasis) where secondary bacterial or candidal infection is present, suspected or likely to occur, as when using occlusive dressings.

Dosage & administration: Adults and children over 2 years:
Apply sparingly to the affected area once or twice daily until improvement occurs. In very resistant lesions, specially where there is hyperkeratosis, the anti-inflammatory effect of **Dermex® NN** can be enhanced, if necessary, by occluding the treatment area with polythene. 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.
Elderly: **Dermex® NN** is suitable for use in the elderly. Caution should be exercised in cases where a decrease in renal function exists and significant systemic absorption of neomycin sulphate may occur.
Children: **Dermex® NN** is suitable for use in children (2 years and over) at the same dose as adults. A possibility of increased absorption exists in very young children, thus **Dermex® NN** is not recommended for use in neonates and infants (younger than 2 years).

Contraindications: Rosacea, acne vulgaris and perioral dermatitis. Primary cutaneous viral infections (eg. herpes simplex, chickenpox). Hypersensitivity to the preparations. Use of this skin preparation is not indicated in the treatment of primary infected skin lesions caused by infection with fungi (eg. candidiasis, tinea), bacteria (eg. impetigo), or yeast; secondary infections due to pseudomonas or proteus species; perianal and genital pruritus, dermatoses in children under 2 years of age, including dermatitis and 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 and infants (upto 2 years).

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 hypercortisolism. This effect is more likely to occur in infants and children and if occlusive dressings are used. Prolonged and intensive treatment with highly active corticosteroid preparations 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. It is usually well tolerated, but if signs of hypersensitivity appear, application should be stopped immediately.

Use in pregnancy & lactation: There is little information to demonstrate the possible effect of topically applied neomycin in pregnancy and lactation. However, neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal toxicity, thus the use of this preparation is not recommended in pregnancy and lactation. The safe use of clobetasol propionate during lactation has not been established.

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. It should be noted that the child's napkin may act as an occlusive dressing. 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. Following significant systemic absorption, aminoglycosides such as neomycin can cause irreversible.

Drug interactions: 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.

Overdosage: Acute overdosage is very unlikely to occur. However, in the case of chronic overdosage or misuse the features of hypercortisolism may appear and in this situation topical steroids should be discontinued gradually. Because of the risk of acute adrenal suppression, this should be done under medical supervision. 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. Blood levels of neomycin sulphate should also be determined. Haemodialysis may reduce the serum level of neomycin sulphate.

Storage: Store in a cool (Below 25˚C temperature) and dry place protected from light.

Packaging: Dermex® NN Cream: Each carton contains a tube having 20 gm cream.

Opsonin Pharma
Ideas for healthcare

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0652-01