Dermasol-N®

Clobetasol Propionate, Neomycin Sulphate & Nystatin

COMPOSITION

Dermasol-N® Cream: Each gram cream contains Clobetasol Propionate BP 0.5 mg, Neomycin Sulphate BP 5 mg and Nystatin BP 100,000 I.U.
Dermasol-N® Ointment: Each gram ointment contains Clobetasol Propionate BP 0.5 mg, Neomycin Sulphate BP 5 mg and Nystatin BP 100,000 I.U.

PHARMACOLOGY

Dermasol-N® 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. The mechanism of the topical steroids like Clobetasol, in general, is unclear. However, Clobetasol Propionate is highly active corticosteroid with topical anti-inflammatory activity. The major effect of Clobetasol Propionate on skin is a nonspecific anti-inflammatory response, partially due to vasoconstriction and decrease in collagen synthesis. 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.

INDICATION

Dermasol-N® is indicated in-

- Short courses treatment of recalcitrant eczemas
- Neurodermatoses
- Psoriasis (excluding widespread plaque psoriasis) where secondary bacterial infection 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: Apply sparingly to the affected area once or twice daily until improvement occurs. In very resistant lesion, specially where there is hyperkeratosis, the anti-inflammatory effect of **Dermasol-N®** 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: **Dermasol-N®** is suitable for use in elderly. Caution should be exercised in cases where a decrease in renal function exists and significant systemic absorption of Neomycin Sulphate may occur.

Children: **Dermasol-N®** 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 **Dermasol-N®** is not recommended for use in neonates and infants (younger than 2 years).

CONTRAINDICATION

This medication is contraindicated in rosacea, acne vulgaris and perioral dermatitis, primary cutaneous viral infection (eg-*Herpes simplex*, chicken pox) and hypersensitivity to the preparation.

PRECAUTION

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 applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If this medication does enter the eye, the affected eye should be thoroughly washed with copious amount of water.

USE IN PREGNANCY AND LACTATION

There is little information to demonstrate the possible effect of topically applied Neomycin in pregnancy and lactation. However, Neomycin present in the maternal blood can cross the placenta and may give rise to a theoretical risk of foetal toxicity, thus the use of the preparation is not recommended in pregnancy and lactation. The safety of Clobetasol Propionate has not been established in lactating mothers.

ADVERSE EFFECT

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. 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.

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.

OVERDOSAGE

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 in this situation topical steroids should be discontinued gradually.

STORAGE CONDITION

Store below 25° C, protected from light.
Do not refrigerate. Keep out of reach of children.

HOW SUPPLIED

Dermasol-N® Cream: Each pack has a laminated tube containing 15 gm cream.
Dermasol-N® Ointment: Each pack has a laminated tube containing 15 gm ointment.

Manufactured by

SQUARE
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH