

Dermastin

Clobetasol Propionate BP, Neomycin Sulfate BP and Nystatin BP cream & ointment

Composition: Dermastin ointment: Each gram Ointment contains Clobetasol Propionate BP 0.5 mg, Neomycin Sulfate BP 5 mg and Nystatin BP 1,00,000 IU. Dermastin cream: Each gram cream contains Clobetasol Propionate BP 0.5 mg, Neomycin Sulfate BP 5 mg and Nystatin BP 1,00,000 IU.

Description: Clobetasol Propionate is a highly active corticosteroid with topical anti-inflammatory activity. 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 Sulfate is a broad spectrum antibiotic of the aminoglycoside type and is used to treat infections with bacteria. Nystatin is an antifungal medicine that kills fungi and yeasts by interfering with their cell membranes. The principle action of the preparation is based on the anti-inflammatory activity of the corticosteroid. The broad spectrum antibacterial and anti-candidal activity provided by the combination of Neomycin and Nystatin allow this effect to be utilized in the treatment of conditions which are or are likely to become infected.

Indication: 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 & 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 Clobetasol Propionate, Neomycin Sulfate & Nystatin 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:** Clobetasol Propionate, Neomycin Sulfate & Nystatin 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 Sulfate may occur. **Children:** Clobetasol Propionate, Neomycin Sulfate & Nystatin 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 Clobetasol Propionate, Neomycin Sulfate & Nystatin is not recommended for use in neonates and infants (younger than 2 years).

Contraindications: It is contraindicated in rosacea, acne vulgaris, perioral dermatitis, primary cutaneous viral infections (eg. herpes simplex, chickenpox), otitis externa, with a perforated eardrum, and hypersensitivity to the preparations. Scalp application is contraindicated in infection of the scalp.

Side effects: Generally this preparation is well tolerated. However, 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.

Use in pregnancy & lactation: Pregnancy category **C**. The safe use of this preparation during pregnancy & 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. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye. If used in psoriasis careful patient supervision is important. **Scalp Application:** Keep away from eye. Flammable. Do not use or dry the hair near a fire or flame.

Drug interactions: Neomycin Sulfate 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 Sulfate 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.

Pediatric use: Clobetasol Propionate, Neomycin Sulfate & Nystatin 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 Dermastin is not recommended for use in neonates and infants (younger than 2 years).

Geriatric use: It 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 Sulfate may occur.

Storage: Store below 25°C temperatures. Do not freeze. Keep out of reach of children.

Packaging: **Dermastin cream:** Each tube contains 15 gm cream. **Dermastin ointment:** Each tube contains 15 gm ointment.



Manufactured by
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