

DERMASTIN

CLOBETASOL PROPIONATE USP; NEOMYCIN SULPHATE BP & NYSTATIN BP

Compositions:

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.

Pharmacology:

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.

Dosage And Administration:

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 with a perforated eardrum and hypersensitivity to the preparations. Scalp application is contraindicated in infection of the scalp.

Warning And 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 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.

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 and Lactation:

Pregnancy category C. The safe use of this preparation during pregnancy & lactation has not been established.

Drug Interaction:

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.

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:

Keep away from light, in dry & cool place. Store below 25°C temperatures. Do not freeze. Keep out of reach of children.

Packing:

Dermastin Cream: Each tube contains 15 gm cream. Dermastin Ointment: Each tube contains 15 gm ointment.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.