

# Exovate® N

Clobetasol Propionate, Neomycin Sulfate and Nystatin Cream

## 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.

The use of Nystatin in the local treatment of candidal infections of the skin and of Neomycin as a broad-spectrum antibiotic is well known.

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 infected or likely to become infected.

## Indications

Exovate® N cream 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 and Administration

For topical administration

*Adults and children over 2 years:*

Apply sparingly to the affected area once or twice daily until improvement occurs. As with other highly active topical steroid preparations therapy should be discontinued when control is achieved. In the more responsive conditions this may be within a few days.

In very resistant lesions, especially where there is hyperkeratosis, the anti-inflammatory effect of cream can be enhanced, if

necessary, by occluding the treatment area with polythene. Overnight occlusion only is usually adequate to bring about a satisfactory response, thereafter improvement can be usually maintained by application without occlusion.

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.

Repeated short courses of cream may be used to control exacerbations. If continuous steroid treatment is necessary, a less potent preparation should be used.

*Dosage in Renal Impairment:* Dosage should be reduced in patients with reduced renal function.

### *Elderly:*

Exovate® N cream 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 Sulfate may occur.

### *Children:*

Exovate® N cream is suitable for use in children (2 years and over) at the same dose as adults.

## Contraindications

Exovate® N cream is contraindicated in rosacea, acne vulgaris and perioral dermatitis, primary cutaneous viral infections (eg. herpes simplex, chickenpox) and hypersensitivity to the preparation. A possibility of increased absorption exists in very young children, thus it is not recommended for use in neonates and infants (younger than 2 years).

## 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 applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If cream 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 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 safe use of Clobetasol Propionate during lactation has not been established.

## Adverse 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.

## Drug Interaction

No overdose related problem yet reported. 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.

## Pharmaceutical Precautions

No special storage or handling precautions apply, although it is recommended that every medicine be kept in a cool, dry place in accordance with good pharmaceutical practice and keep out of reach of children.

## Commercial Pack

Exovate® N cream : Tube containing 25 g cream, each gram contains Clobetasol Propionate BP0.05% w/w, Neomycin Sulfate USP0.5% and Nystatin BP1,00,000 units.



Manufactured by

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