

UNIDERM NM

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for UNIDERM NM [Clobetasol Propionate, Neomycin Sulphate and Miconazole Nitrate Cream]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Clobetasol Propionate:* The mechanism of anti-inflammatory activity of the topical corticosteroids involves induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. Clobetasol propionate also produces anti-inflammatory response, partially due to vasoconstriction and decrease in collagen synthesis. *Neomycin Sulphate:* Neomycin exerts its bactericidal effect by interfering with the protein synthesis of susceptible organisms. Neomycin is rapidly acting bactericidal agent; after diffusing through the bacterial cell membrane, it binds polysomes to affect protein synthesis. *Miconazole Nitrate:* Miconazole is an imidazole antifungal agent that acts by interfering with the permeability of the fungal cell membrane. Miconazole inhibits biosynthesis of ergosterol, damaging the fungal cell wall, which increases permeability causing leakage of nutrients.

INDICATIONS: For use only in condition of severe Acute Uveitis in adults only. *Remark:* FDC shall not be used continuously for more than one week without re-evaluation by the physician.

DOSAGE AND ADMINISTRATION: Sufficient amount of cream should be applied to cover the affected areas twice daily (morning and evening). Rub the cream in gently and completely. *Method of administration:* For topical use in adults and children over 2 years of age.

CONTRAINDICATION: UNIDERM NM Cream is contraindicated in cases: •Hypersensitivity to clobetasol or to neomycin or to miconazole or to any component of the formulation •Rosacea •Acne vulgaris •Perioral dermatitis •Perianal and genital pruritus •Primary cutaneous viral infections (e.g., herpes simplex, chickenpox) •Otitis externa with a perforated eardrum (because of risk of ototoxicity).

WARNINGS & PRECAUTIONS: *Clobetasol Propionate:* Use of potent topical corticosteroids, including clobetasol propionate, should be avoided on areas with thin and sensitive skin, such as on the face, groin or in the skin folds. Long-term continuous therapy should be avoided. Children are at greater risk of adrenal insufficiency after withdrawal of treatment, and of Cushing's syndrome while on treatment. *Neomycin Sulphate:* Serious adverse reactions including neurotoxicity, ototoxicity and nephrotoxicity have occurred in patients receiving systemic aminoglycoside therapy. Although these effects have not been reported following topical use of aminoglycosides, caution is advised when used concomitantly with systemic aminoglycosides. Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. *Miconazole Nitrate:* Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with miconazole topical formulations. If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued.

DRUG INTERACTIONS: *Clobetasol Propionate:* CYP3A4 inhibitor drugs such as ritonavir and itraconazole, when co-administered with corticosteroids have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. *Neomycin Sulphate:* Neomycin sulphate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents. Concurrent use with other potentially nephrotoxic or ototoxic drugs should be avoided unless considered essential by the physician. *Miconazole Nitrate:* Miconazole administered systemically is known to inhibit CYP3A4/2C9. In patients on oral anticoagulants, such as warfarin, caution should be exercised, and anticoagulant effect should be monitored.

ADVERSE REACTIONS: *Clobetasol Propionate:* Hypersensitivity, Features of Cushing's Syndrome, Dilatation of the Superficial Blood Vessels, Tissue Disorders. *Neomycin Sulphate:* Skin sensitization, Ototoxicity and Nephrotoxicity. *Miconazole Nitrate:* Itching, burning, rash, and contact dermatitis.

MARKETED BY:



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(Additional information is available on request)