

BETAMED - N

Topical Corticosteroid with Antimicrobial
(Betamethasone Valerate)
(Neomycin Sulphate)



PHARMACEUTICAL PRESENTATIONS:

BETAMED - N CREAM

BETAMED - N OINTMENT

COMPOSITION:

0.1% w/w Betamethasone as the valerate ester and 0.5% w/w Neomycin sulphate in cream and ointment base.

Inactive Ingredients for Betamed-N Cream: Cetostearyl alcohol, Cetomacrogol 1000, Methyl paraben, Propyl paraben, Liquid paraffin, Monobasic sodium phosphate dihydrate, White petrolatum and Purified water.

Inactive Ingredients for Betamed-N Ointment: Cetostearyl alcohol, Cetomacrogol 1000, Liquid paraffin and White petrolatum.

PROPERTIES:

Betamed - N is a combination therapy of Betamethasone which is a medium glucocorticoid used in moderate inflammatory diseases and eczematous dermatosis and Neomycin sulphate which is an aminoglycoside antibiotic that has a bactericidal action against many gram-negative aerobes and against some strains of staphylococci. Neomycin Sulphate used topically in the treatment of infections of the skin due to susceptible microorganisms.

INDICATIONS:

Eczema, including atopic, infantile and discoid eczema; psoriasis; neurodermatoses, seborrheic dermatitis; contact sensitivity reactions and insect bites when infection is present or suspected.

CONTRA - INDICATIONS:

The product is contra-indicated in case of: Rosacea, acne and perioral dermatitis, primary cutaneous viral reactions eg. Herpes simplex, chicken pox, hypersensitivity to any of its components. The use of betamethasone is not indicated in the treatment of primarily infected skin lesions caused by infections with fungi. eg. Candidiasis, tinea..

Primary or secondary infections due to yeast, peri-anal and genital pruritus, dermatoses in children under 1 year of age including dermatitis and napkin eruptions.

WARNINGS AND PRECAUTIONS:

- Long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression, with or without clinical features of Cushing's syndrome, can occur even without occlusion. In this situation, topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency
- The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result.
- If used in childhood, or on the face, courses should be limited to five days and occlusion should not be used.

- Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important.
- Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic administration of antimicrobial agents. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and so the skin should be cleansed before a fresh dressing is applied.

OVERDOSAGE:

Acute over dosage is very unlikely to occur, however in the case of chronic over dosage or misuse the features of hypercortism may appear and in this situation topical steroids should be discontinued.

ADVERSE EFFECTS:

Infrequently, burning sensation, skin rashes, itching, irritation, dryness, folliculitis, acneform eruptions, hypopigmentation and perioral dermatitis may occur.

STORAGE: Store at room temperature not exceeding 25°C.

- ♦ Do not use after the expiry date stated on the pack.
- ♦ Do not use if there is any physical change on the product

PACKAGING PRESENTATIONS:

BETAMED-N CREAM: Collapsible Aluminum tube of 30gm

BETAMED-N OINTMENT: Collapsible Aluminum tube of 30gm.

THIS IS A MEDICAMENT

Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

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