COMPOSITION
Betameson-N® cream: Each gram contains Betamethasone dipropionate USP equivalent to 1mg Betamethasone base and Neomycin sulphate BP 5mg.

PHARMACOLOGY
Betamethasone is an active topical corticosteroid which produces a rapid response in those inflammatory dermatoses that are normally responsive to topical corticosteroid therapy, and is often effective in the less responsive conditions such as psoriasis.

Neomycin sulphate is a broad spectrum bactericidal antibiotic effective against the majority of bacteria commonly associated with skin infections.

INDICATION
Betameson-N® cream is indicated for the treatment of the following conditions where secondary bacterial infection is present, suspected, or likely to occur:

- Eczema in children and adults, including atopic and discoid eczemas; prurigo nodularis; psoriasis (excluding widespread plaque psoriasis);
- Neurodermatoses, seborrhoeic dermatitis; contact sensitivity reactions. It may be used as an adjunct to systemic steroid therapy in generalized erythroderma. It can also be used in the management of secondarily infected insect bites and anal and genital intertrigo.

DOSAGE AND ADMINISTRATION
A small quantity should be applied gently to the affected area two or three times daily until improvement occurs. It may then be possible to maintain improvement by applying once a day, or even less often.

CONTRAINDICATION AND PRECAUTION
The combination is contraindicated in rosacea, acne vulgaris and perioral dermatitis, primary cutaneous viral infections (e.g. herpes simplex, chicken pox). It is also contraindicated in patients hypersensitive to any of its components.

Application to large areas especially during pregnancy, in the elderly and in patients with impaired renal function is not advisable due to a risk of ototoxicity.
Use of the combination cream is not indicated in the treatment of primarily infected skin lesions caused by infection with fungi (e.g. candidiasis, tinea), or bacteria (e.g. impetigo), primary or secondary infections due to Pseudomonas or Proteus species; perianal and genital pruritus; dermatoses in children under 1 year of age, including dermatitis and napkin eruptions.

Preparations containing neomycin should not be used for the treatment of otitis externa when the ear drum is perforated, because of the risk of ototoxicity.

Long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur even without occlusion.

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 with the combination. 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. If it is used in psoriasis careful patient supervision is important.

Do not continue for more than 7 days in the absence of clinical improvement, since occult extension of infection may occur due to the masking effect of the steroid.

**SIDE EFFECT**

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.

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 hypercorticism and suppression of the HPA axis.

**USE IN PREGNANCY AND LACTATION**

There is inadequate evidence of safety in human pregnancy. Topical
administration of corticosteroids to pregnant animal can cause abnormalities of fetal development including cleft palate and intrauterine growth retardation. There may therefore be a very small risk of such effects in the human fetus. The use of neomycin may be associated with a theoretical risk of fetal ototoxicity.

**STORAGE CONDITION**
Protect from light and moisture. Keep out of reach of children.

**HOW SUPPLIED**
Betameson-N® cream: Tube containing 5gm topical cream.