

Betnovate-N skin preparations

Trade mark

M57002(02)
0987

Presentation

The Betnovate-N skin preparations contain 0.1% betamethasone as the valerate ester and 0.5% neomycin sulphate (3,500 units per gram or per ml).

Betnovate-N cream is a smooth, white, water-miscible cream.

Betnovate-N ointment is a white, paraffin-based ointment.

Betnovate-N lotion is a white, aqueous, translucent fluid.

Uses

Betamethasone valerate 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.

Betnovate-N preparations are indicated for the treatment of the following conditions where secondary bacterial infection is present, suspected, or likely to occur: eczema, including atopic, infantile, discoid and stasis eczemas; prurigo; psoriasis (excluding widespread plaque psoriasis); neurodermatoses, including lichen simplex; lichen planus; seborrhoeic dermatitis; intertrigo; contact sensitivity reactions; discoid lupus erythematosus; generalised erythroderma.

Betnovate-N preparations can also be used in the management of insect bites, sunburn, prickly heat, anal and vulval pruritus, and otitis externa (see 'Contra-indications').

Dosage and administration

A small quantity should be applied 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. Betnovate-N cream is especially appropriate for moist or weeping surfaces, and Betnovate-N ointment for dry, lichenified or scaly lesions, but this is not invariably so. Betnovate-N lotion is particularly suitable when a minimal application to a large area is required.

In the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effect of Betnovate-N can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response in such cases, thereafter improvement can usually be maintained by regular application without occlusion.

Contra-indications

Dermatoses in children under one year of age, including dermatitis and napkin eruptions.

Rosacea, acne and per-oral dermatitis. Skin lesions caused by infection with viruses (e.g., herpes simplex, chickenpox), fungi (e.g., candidiasis, tinea) or bacteria (e.g., impetigo). 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. Hypersensitivity to the preparations.

Precautions

Topical steroids 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.

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 Betnovate. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result.

Application to large areas in the elderly and in patients with impaired renal function can carry a risk of ototoxicity. Products which contain antimicrobial agents should not be diluted.

If bacterial infection persists, systemic chemotherapy is required. Any spread of infection requires withdrawal of topical corticosteroid therapy. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and the skin should be cleansed before a fresh dressing is applied.

Pregnancy

The use of neomycin may be associated with a theoretical risk of fetal ototoxicity.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development.

The relevance of this finding to human beings has not been established; however, topical steroids should not be used extensively in pregnancy, i.e., in large amounts or for prolonged periods.

Side effects

Prolonged and intensive treatment with highly active corticosteroid preparations may cause local atrophic changes in the skin such as striae, thinning 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. This effect is more likely to occur in infants and children, and if occlusive dressings are used. In infants, the napkin may act as an occlusive dressing.

The Betnovate preparations are usually well tolerated, but if signs of hypersensitivity appear, application should stop immediately.

In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.

Pharmaceutical precautions

Store below 30°C.

Further information

The least potent corticosteroid which will control the disease should be selected. These preparations do not contain lanolin. Betnovate-N cream and Betnovate-N ointment do not contain parabens.

Glaxo

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