BETNOVATE™
CREAM AND OINTMENT

Betamethasone 17-valerate for dermatological use.

PRESENTATION

Betnovate Cream (non-greasy base)
0.1% betamethasone as 17-valerate in a water-miscible cream base.

Betnovate Ointment (greasy base)
0.1% betamethasone as 17-valerate in a bland ointment base.

Betnovate Cream contains Chlorocresol 0.1% w/w as preservative.

INDICATIONS

- Eczema including atopic, infantile, and discoid eczemas.
- Prurigo nodularis.
- Psoriasis (excluding widespread plaque psoriasis).
- Neurodermatoses including lichen simplex, lichen planus.
- Seborrhoeic dermatitis.
- Contact sensitivity reactions.
- Discoid lupus erythematosus.
- An adjunct to systemic steroid therapy in generalised erythroderma.
- Insect bite reactions.
- Prickly heat.

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 creams are especially appropriate for moist or weeping surfaces and Betnovate ointments for dry, lichenified or scaly lesions, but this is not invariably so.
In the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effect of Betnovate 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 lesions thereafter, improvement can usually be maintained by regular application without occlusion.

CONTRA-INDICATIONS

- Rosacea.
- Acne vulgaris.
- Perioral dermatitis.
- Perianal and genital pruritus.
- Primary cutaneous viral infections (e.g. herpes simplex, chickenpox).
- Hypersensitivity to the preparations.

The use of Betnovate skin preparations is not indicated in the treatment of primarily infected skin lesions caused by infection with fungi or bacteria, dermatoses in children under one year of age, including dermatitis and napkin eruptions.

PRECAUTIONS

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.
If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result.
Topical steroids may be hazardous in psoriasis for a number of reasons, including rebound relapses, development of tolerances, 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.

PREGNANCY

Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal 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

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10,000 and <1/1000) and very rare (<1/10,000) including isolated reports. Very common, common and uncommon events were generally determined from clinical trial data. The background rates in placebo and comparator groups were not taken into account when assigning frequency categories to adverse events derived from clinical trial data, since these rates were generally comparable to those in the active treatment group. Rare and very rare events were generally determined from spontaneous data.

Immune System Disorders

Very rare: Hypersensitivity.

If signs of hypersensitivity appear, application should stop immediately.

Endocrine Disorders

Very rare: Features of hypercortisolism.

As with other 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. In infants, the napkin may act as an occlusive dressing.

Vascular Disorders

Very rare: Dilatation of the superficial blood vessels.

Prolonged and intensive treatment with highly active corticosteroid preparations may cause dilatation of the superficial blood vessels, particularly when occlusive dressings are used or when skin folds are involved.

Skin and Subcutaneous Tissue Disorders

Common: Local skin burning and pruritus.

Very rare: Thinning, striae, pigmentation changes, hypertrichosis, allergic contact dermatitis, pustular psoriasis, exacerbation of symptoms.

Prolonged and intensive treatment with highly active corticosteroid preparations may cause local atrophic changes in the skin such as thinning and striae, particularly when occlusive dressings are used or when skin folds are involved.

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

OVERDOSAGE

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may appear and in this situation topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency.

PHARMACEUTICAL PRECAUTIONS

Store below 30 °C.

DATE OF APPROVAL/REVISION

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