

Betnovate™ Scalp Application

Betamethasone

To the Medical and Pharmaceutical Professions.

Presentation

1 g solution contains 1.22 mg betamethasone valerate, equivalent to 1 mg betamethasone

Indications

Steroid responsive dermatoses of the scalp such as psoriasis, seborrhoea capitis, inflammation associated with severe dandruff.

Dosage and Administration

A small quantity of Betnovate Scalp Application should be applied to the scalp night and morning until improvement is noticeable. It may then be possible to sustain improvement by applying once a day, or less frequently to about 3 to 4 times a week. Betnovate Scalp Application is supplied in bottles with a dropper. It can thus be applied directly to the area of scalp to be treated without wetting the hair completely.

Contra-indications

Infections of the scalp. Betnovate Scalp Application is not intended for use on the face.

Hypersensitivity to any ingredient of the preparation.

Use is not indicated in dermatoses in children under one year of age, including dermatitis.

Betnovate scalp application must not be used in extensive chronic stationary forms of psoriasis.

Precautions and Warnings

Care must be taken to keep the preparation away from the eyes.

Do not use near a naked flame.

Betnovate scalp application should be used only for a short time (for less than 1 week) and on small areas (less than 10% of the body surface area) in children. In general, greater caution is advisable in the treatment of children with corticosteroid products, since compared to adults, there can be a higher uptake of the corticosteroid through children's skin.

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.

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. 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 and Lactation

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.

Glucocorticoids pass into the breast milk. No damage to the infant has so far come to light. However, the product should not be used during breast-feeding unless strictly indicated. Contact between the infant and the treated body areas is to be avoided. If higher doses are necessary for the disease, the infant should be weaned.

Adverse Reactions

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$ and $< 1/10$), uncommon ($\geq 1/1000$ and $< 1/100$), rare ($\geq 1/10,000$ 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 be stopped 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.

Skin and subcutaneous tissue disorders:

Uncommon: stinging and pruritus.

Very rare: Local atrophic changes, allergic contact dermatitis, pustular psoriasis.

During prolonged use or use on a large area, especially under occlusion or in skin folds, changes can occur in the treated area of skin, such as thinning of the skin, striae, steroid acne, teleangiectases, changes in skin pigmentation and hypertrichosis.

Local atrophy may occur after prolonged treatment.

In very rare instances, treatment of psoriasis with corticosteroids (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 and Recommendations

Do not store above 25°C.

List of Excipients

Carbomer

Isopropyl Alcohol

Sodium Hydroxide

Purified Water

Manufactured by:

Aspen Bad Oldesloe GmbH

Bad Oldesloe

Germany

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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 the 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.