

BETA SCALP APPLICATION

Betamethasone valerate



DATA SHEET

Presentation

BETA Scalp Application is a transparent, slightly gelled solution containing 0.1% w/w betamethasone as the valerate ester.

Uses

Actions

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.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolised primarily by the liver and are then excreted by the kidneys.

Indications

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

Dosage and Administration

A small quantity of BETA 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.

Contraindications

Infections of the scalp, viral disease of the skin (herpes, chickenpox), fungal infections (moniliasis) and ulcerative conditions.

Hypersensitivity to the preparation.

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

The use of fluorinated steroids is contraindicated on the face.

Warnings and Precautions

Care must be taken to keep the preparation away from the eyes. Do not use near a naked flame.

Long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression, with or without Cushing's syndrome, can occur even without occlusion. In this situation, topical corticosteroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency (see Adverse Effects and Overdosage).

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.

Development of secondary infection requires withdrawal of topical corticosteroid therapy and commencement of appropriate systemic antimicrobial therapy.

The least potent corticosteroid which will control the disease should be selected.

Pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities to foetal development including cleft palate and intrauterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.

Adverse Effects

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 Cushing's syndrome

As with other topical corticosteroids, prolonged use of large amounts or treatment of extensive areas can result in sufficient systemic absorption to produce suppression of the HPA axis and the clinical features of Cushing's syndrome (see Warnings and Precautions). These effects are more likely to occur in infants and children, and if occlusive dressings are used.

Skin and subcutaneous tissue disorders

Common: Local skin burning and pruritus.

Very rare: Local atrophic changes in the skin such as thinning, striae and dilatation of the superficial blood vessels may be caused by prolonged and intensive treatment with highly active corticosteroid preparations, particularly when occlusive dressings are used or when skin folds are involved.

Pigmentation changes, hypertrichosis, allergic contact dermatitis, exacerbation of symptoms, pustular psoriasis (due to treatment of psoriasis with corticosteroids or its withdrawal: see Warnings and Precautions).

Interactions

None known.

Overdosage

Acute overdosage is unlikely to occur. However, in the case of chronic overdosage or misuse, the features of Cushing's syndrome may appear and in this situation topical corticosteroids should be discontinued gradually under medical supervision (See Warnings and Precautions).

Pharmaceutical Precautions

Store below 25°C. Keep container tightly closed.

Medicine Classification

Prescription Medicine.

Package Quantities

Plastic squeeze bottles of 100mL and 250mL.

Not all pack sizes may be marketed.

Further Information

This product also contains isopropyl alcohol, sodium hydroxide, carbomer 934P and purified water.

Name and Address

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