BETNOVATE™ SCALP APPLICATION

PRESENTATION

Betnovate Scalp Application is a transparent, slightly gelled solution containing 0.1% w/w betamethasone as valerate. The vehicle contains 50% of isopropyl alcohol, which has antibacterial activity. This preparation complies with the specifications for Betamethasone Valerate Scalp Application BP.

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.

CONTRA-INDICATIONS

Infections of the scalp.
Hypersensitivity to the preparation.
Use is not indicated in dermatoses in children under one year of age, including dermatitis.

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 can occur even without occlusion.
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.
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.
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

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 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

Common: Local skin burning and pruritus.

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

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.

INSTRUCTIONS FOR USE/HANDLING

Keep away from eyes.
Flammable. Do not use or dry the hair near a fire or naked flame.
Keep all medicines out of the reach of children.

DIRECTIONS FOR USE

This preparation has been specially produced for application directly on to the scalp from the squeeze bottle.
Remove the cap, then introduce the nozzle through the hair and on to the affected area of scalp.

Squeeze the bottle gently allowing the liquid to spread until the affected area is completely covered. You will experience a cooling sensation as the liquid evaporates leaving the active medicament on the scalp. Your hair will be unaffected. If necessary, Betnovate Scalp Application may be massaged into the scalp using the tips of the fingers.
Apply twice daily to the affected area of scalp or as directed by your doctor.
When washing or shampooing the hair, apply Betnovate Scalp Application **after** this procedure has been carried out. Application to parts of the body other than the scalp should be made only on the advice of your doctor.

PHARMACEUTICAL PRECAUTIONS

Store below 25°C.

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