

SUMMARY OF PRODUCT CHARACTERISTICS

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1 NAME OF THE MEDICINAL PRODUCT

Betnovate Scalp Application.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone Valerate BP 0.122% w/w.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Aqueous Suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and Method of 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.

For topical application.

This product is flammable. Keep the liquid away from open fire and flames and all sources of ignition including smoking during application and immediately after use.

Paediatric population

Betamethasone valerate is contraindicated in children under one year of age.

Children are more likely to develop local and systemic side effects of topical corticosteroids and, in general, require shorter courses and less potent agents than adults; therefore, courses should be limited to five days and occlusion should not be used.

Care should be taken when using betamethasone valerate to ensure the amount applied is the minimum that provides therapeutic benefit.

Elderly

Clinical studies have not identified differences in responses between the elderly and younger patients.

The greater frequency of decreased hepatic or renal function in the elderly may delay elimination if systemic absorption occurs. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

Renal / Hepatic Impairment

In case of systemic absorption (when application is over a large surface area for a prolonged period) metabolism and elimination may be delayed therefore increasing the risk of systemic toxicity. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

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4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients listed in section 6.1.

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

4.4 Special warnings and precautions for use

Betamethasone valerate should be used with caution in patients with a history of local hypersensitivity to other corticosteroids. Local hypersensitivity reactions (*see section 4.8*) may resemble symptoms of the condition under treatment.

Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids. If either of the above are observed, withdraw the drug gradually by reducing the frequency of application, or by substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency (*see section 4.8*).

Risk factors for increased systemic effects are:

- Potency and formulation of topical steroid
- Duration of exposure
- Application to a large surface area
- Increasing hydration of the stratum corneum
- Use on occluded areas of the skin
- Use on thin skin areas
- Use on broken skin or other conditions where the skin barrier may be impaired
- In comparison with adults, children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects. This is because children have an immature skin barrier and a greater surface area to body weight ratio compared with adults.

Paediatric population

In infants and children under 12 years of age, treatment courses should be limited to five days and occlusion should not be used; long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression can occur.

Infection risk with occlusion

Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied.

Use in Psoriasis

Topical corticosteroids should be used with caution in psoriasis as rebound relapses, development of tolerances, risk of generalised pustular psoriasis and development of local or systemic toxicity due to

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impaired barrier function of the skin have been reported in some cases. If used in psoriasis careful patient supervision is important.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Scalp Application

Patients should be advised to:

- Keep the preparation away from the eyes
- avoid smoking whilst applying Betnovate scalp application
- avoid fire, flame and heat including use of hair dryer after application

4.5. Interactions with other Medicaments and other forms of Interaction

Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

4.6 Fertility, pregnancy and lactation

Fertility

There are no data in humans to evaluate the effect of topical corticosteroids on fertility.

Pregnancy

There are limited data from the use of betamethasone valerate in pregnant women.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. (*see section 5.3*).

The relevance of this finding to humans has not been established; however, administration of betamethasone valerate during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. The minimum quantity should be used for the minimum duration.

Lactation

The safe use of topical corticosteroids during lactation has not been established.

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Administration of betamethasone valerate during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation betamethasone valerate should not be applied to the breasts to avoid accidental ingestion by the infant.

4.7 Effects on ability to drive and use machines

There have been no studies to investigate the effect of betamethasone valerate on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical betamethasone valerate.

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4.8 Undesirable effects

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$ and $< 1/10$), uncommon ($\geq 1/1,000$ and $< 1/100$), rare ($\geq 1/10,000$ and $< 1/1,000$) and very rare ($< 1/10,000$), including isolated reports.

Post-marketing data

Infections and Infestations

Very rare Opportunistic infection

Immune System Disorders

Very rare Hypersensitivity, generalised rash

Endocrine Disorders

Very rare Hypothalamic-pituitary adrenal (HPA) axis suppression

Cushingoid features (e.g. moon face, central obesity),
delayed weight gain/growth retardation in children,
osteoporosis, glaucoma, hyperglycaemia/glucosuria,
cataract, hypertension, increased weight/obesity,
decreased endogenous cortisol levels, alopecia,
trichorrhhexis

Skin and Subcutaneous Tissue Disorders

Common Pruritus, local skin burning /skin pain

Very rare Allergic contact dermatitis /dermatitis, erythema, rash,
urticaria, pustular psoriasis, skin thinning* / skin atrophy*,
skin wrinkling*, skin dryness*, striae*, telangiectasias*,
pigmentation changes*, hypertrichosis, exacerbation of
underlying symptoms

General Disorders and Administration Site Conditions

Very rare Application site irritation/pain

**Skin features secondary to local and/or systemic effects of hypothalamic-pituitary adrenal (HPA) axis suppression.*

Eye disorders

Not known Vision, blurred (see also section 4.4)

Reporting of suspected reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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4.9. Overdose

Symptoms and signs

Topically applied betamethasone valerate may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur (*see section 4.8*).

Treatment

In the event of overdose, betamethasone valerate should be withdrawn gradually by reducing the frequency of application, or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code

D07AC Corticosteroids, potent (group III)

Mechanism of action

Topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid.

Pharmacodynamic effects

Topical corticosteroids have anti-inflammatory, antipruritic, and vasoconstrictive properties.

5.2 Pharmacokinetic properties

Absorption

Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.

Distribution

The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary because circulating levels are well below the level of detection.

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Metabolism

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver.

Elimination

Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

5.3 Preclinical safety data

Reproductive toxicity

Subcutaneous administration of betamethasone valerate to mice or rats at doses ≥ 0.1 mg/kg/day or rabbits at doses ≥ 12 micrograms/kg/day during pregnancy produced foetal abnormalities including cleft palate and intrauterine growth retardation.

The effect on fertility of betamethasone valerate has not been evaluated in animals.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Carbomer
Isopropyl Alcohol
Sodium Hydroxide
Purified Water.

6.2. Incompatibilities

None known.

6.3. Shelf life

24 months.

6.4. Special Precautions for Storage

Store below 25°C

Keep container tightly closed when not in use. Contents are flammable. Keep away from fire, flame or heat. Do not leave Betnovate Scalp Application in direct sunlight.

6.5 Nature and contents of container

White High Density Polyethylene (HDPE) bottle with a white Low Density Polyethylene (LDPE) nozzle and a white HDPE screw cap.

Pack size: 30 mL; 100 mL

Not all pack sizes may be marketed

6.6 Special precautions for disposal

No special requirements.

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- 7** **MARKETING AUTHORISATION HOLDER**
Glaxo Wellcome UK Ltd.
Trading as GlaxoSmithKline UK
GSK Medicines Research Centre
Gunnels Wood Road
Stevenage
Hertfordshire
SG1 2NY
UK
- 8.** **MARKETING AUTHORISATION NUMBER(S)**
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- 9.** **DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION**
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- 10** **DATE OF REVISION OF THE TEXT**
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