# BETNOVATE Scalp Application

## QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone 17-valerate 0.122 % w/w

## CLINICAL INFORMATION

### Indications

Steroid-responsive dermatoses of the scalp such as psoriasis (excluding widespread plaque psoriasis), seborrhoea capitis, inflammation associated with severe dandruff.

### Dosage and Administration

A small quantity of BETNOVATE 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.

Due to the flammable nature of BETNOVATE Scalp Application, patients should avoid smoking or being near an open flame during application and immediately after use.

### Children

BETNOVATE 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.

Care should be taken when using BETNOVATE 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.

**Contraindications**

Infections of the scalp

BETNOVATE is contraindicated in dermatoses in infants under one year of age, including dermatitis.

**Precautions and Warnings**

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

BETNOVATE should be used with caution in patients with a history of local hypersensitivity to corticosteroids or to any of the excipients in the preparation. Local hypersensitivity reactions (see Adverse Reactions) 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 Adverse Reactions).

Risk factors for increased systemic effects are:

- Potency and formulation of topical steroid
- Duration of exposure
- Application to a large surface area
- Use on occluded areas of skin e.g. on intertriginous areas or under occlusive dressings
- Increasing hydration of the stratum corneum
- Use on thin skin areas such as the face
- 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.

Visual disturbance which may include cataract, glaucoma or central serous chorioretinopathy has been reported by patients using systemic and / or topical corticosteroids. If a patient has blurred vision or other visual disturbances, consider evaluation of possible causes.

**Children**

In infants and children under 12 years of age, 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 cleaned 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 impaired barrier function of the skin have been reported in some cases. If used in psoriasis careful patient supervision is important.

**Concomitant infection**

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 administration of appropriate antimicrobial therapy.

**Interactions**

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.

**Pregnancy and Lactation**

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

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development (see Pre-Clinical Safety Data).

The relevance of this finding to human beings has not been established; however, administration of BETNOVATE 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.

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

BETNOVATE during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

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

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

**Effects on Ability to Drive and Use Machines**

There have been no studies to investigate the effect of BETNOVATE 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 BETNOVATE.

**Adverse Reactions**

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1,000 and <1/100), rare (≥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 | Local hypersensitivity |

**Endocrine Disorders**

| | |
|---|---|
| Very rare | Hypothalamic-pituitary-adrenal (HPA) axis suppression shingoid 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, trichorrhexis |

**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.*

**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 Adverse Reactions).

**Treatment**

In the event of overdose, BETNOVATE 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.

## PHARMACOLOGICAL PROPERTIES

**Pharmacodynamics**
**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.

## Pharmacokinetics

### 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.

### 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.

## Pre-Clinical Safety Data

***Carcinogenesis/Mutagenesis***

### Carcinogenesis

Long-term animal studies have not been performed to evaluate the carcinogenic potential of betamethasone valerate.

### Genotoxicity

No specific studies have been conducted to investigate the genotoxic potential of betamethasone valerate

### Fertility

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

### Pregnancy

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.

# PHARMACEUTICAL PARTICULARS

### List of Excipients

Carbomer

Isopropyl alcohol

Sodium hydroxide

Purified water

### Incompatibilities

No incompatibilities have been identified.

### Shelf Life

The expiry date is indicated on the packaging.

### Special Precautions for Storage

Store below 25° C. The storage conditions depend on the locally registered shelf-life (refer to the pack for information). 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.

### Nature and Contents of Container

Polyethylene squeeze bottle with a polyethylene nozzle and a polyethylene cap

### Instructions for Use/Handling

There are no special requirements for use or handling of this product.

# MARKETING AUTHORIZATION HOLDER

GLAXOSMITHKLINE (THAILAND) LTD.

## MARKETING AUTHORIZATION NUMBER

1C 233/44

## DATE OF AUTHORIZATION

17 December 2001

## DATE OF REVISION OF THE TEXT

21 September 2020

**Version number: GDS10/IPI05**

**Date of issue: 11 June 2020**

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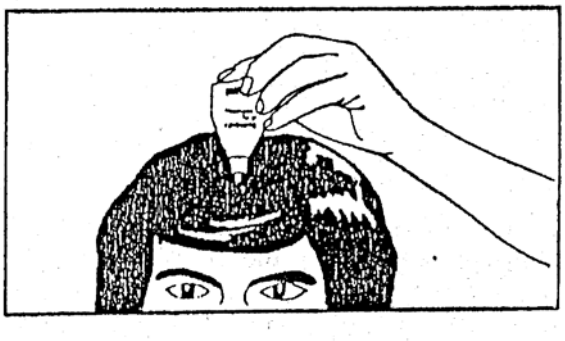
**BETNOVATE SCALP 5.0 TH**

# BETNOVATE Scalp Application

This preparation has been specially produced for application directly onto the scalp from the squeeze bottle.

**Directions for use**

Remove the cap, then introduce the nozzle through the hair and onto 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.

**Precautions**

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.