NEW ZEALAND DATA SHEET

BETA SCALP APPLICATION

1. Product Name

Beta Scalp Application, 0.1% w/w, scalp lotion.

2. Qualitative and Quantitative Composition

Beta Scalp Application contains 0.1% w/w betamethasone as the valerate ester.

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

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

4. Clinical Particulars

4.1 Therapeutic indications

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

4.2 Dose and method of administration

Dose

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.

Special populations

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 beneficial effect.

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 (where 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.

Method of administration

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.

4.3 Contraindications

Hypersensitivity to the active ingredient, betamethasone valerate, or any of the excipients listed in section 6.1.

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

Infections of the scalp.

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 medicine 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 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 Beta Scalp Application to the scalp
- avoid fire, flame and heat including use of hair dryer after application

4.5 Interaction with other medicines and other forms of interaction

Co-administered medicines 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

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.

Fertility

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

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.

4.8 Undesirable effects

Adverse events are listed below by MedDRA 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.

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, 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[1] / skin atrophy[1], skin wrinkling[1], skin dryness[1], striae[1], telangiectasias[1], pigmentation changes, hypertrichosis, exacerbation of underlying symptoms

General disorders and administration site conditions

Very rare: Application site irritation/pain

Eye disorders

Not known: Vision, blurred (see section 4.4)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

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

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 Information Centre.

For further advice on management of overdose please contact the National Poisons Information Centre (0800 POISON or 0800 764 766).

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, potent (group III),

ATC code: D07AC01

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.

Metabolism

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

Beta Scalp Application also contains

- isopropyl alcohol,
- sodium hydroxide,
- carbomer 934P and
- purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or 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 MDPE bottles with LDPE plug and white PP cap. Pack sizes of 100 mL or 250 mL.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7. Medicines Schedule

Prescription Medicine

8. Sponsor Details

Viatris Ltd
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Ellerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

9. Date of First Approval

22 November 1986

10. Date of Revision of the Text

13 March 2023

Summary table of changes

Section	Summary of new information
Header	Updated sponsor name and logo.
6.4	Minor editorial change.
8	Updated sponsor details.