Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Betnovate Scalp Application 0.1% w/w Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml of cutaneous solution contains 0.01 g betamethasone (0.1% w/w) as betamethasone valerate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution
A colourless, hazy, slightly viscous liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Betnovate Scalp Application is a topical corticosteroid used in the management of steroid-responsive dermatoses of the scalp, such as psoriasis, seborrhoea capitis and inflammation associated with severe dandruff.

4.2 Posology and method of administration

Posology

Adults, Elderly and Children over 1 year
A small quantity of Betnovate Scalp Application should be applied to the scalp night and morning until improvement is noticeable for up to 4 weeks. It may then be possible to sustain improvement by applying once a day, or even 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.

Administration in Children
Betamethasone valerate is contraindicated in children under 1 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 betamethasone valerate to ensure the amount applied is the minimum that provides therapeutic benefit.

Administration in the Elderly
Clinical studies have not identified differences in responses between the elderly and younger patients. Since renal and hepatic dysfunctions are more common in the elderly population, elimination could be reduced in the case of systemic absorption. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

Administration in 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.

4.3 Contraindications

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

Infections of the scalp.

Betamethasone valerate is contraindicated in dermatoses in infants under 1 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 corticosteroids or to any of the excipients in the preparation. 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
- Use on occluded areas of skin (e.g. on intertriginous areas or under occlusive dressings) (in infants the nappy may act as an occlusive dressing)
- 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.
Paediatric population
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 cleansed before a fresh dressing 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.

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

There have been a few reports in the literature of the development of cataracts in patients who have been using corticosteroids for prolonged periods of time. Although it is not possible to rule out systemic corticosteroids as a known factor, prescribers should be aware of the possible role of corticosteroids in cataract development.

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.

4.5 Interaction with other medicinal products and other forms of interaction

Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir and 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

Breast-feeding
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 reactions are listed below by MedDRA system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100),
rare ([3]1/10,000 to <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 Local hypersensitivity

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*/skin atrophy*, skin wrinkling*, skin dryness*, striae*, telangiectasias*, pigmentation changes*, hypertrichosis, exacerbation of underlying symptoms

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

General Disorders and Administration Site Conditions
Very rare Application site irritation/pain

Eye disorders
Not known Vision, blurred (see also section 4.4)

Reporting of suspected adverse 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 HPRA Pharmacovigilance,
Website: www.hpra.ie.

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).

Management
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

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 l 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
Because circulating levels of topical corticosteroids are well below the level of detection, it is necessary to use endpoints that assess signs of drug effect to evaluate systemic exposure.

Metabolism
Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systematically 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

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.

Reproductive Toxicology

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Isopropyl alcohol
Sodium hydroxide (for pH adjustment)
Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original package. Protect from light. Protect from moisture.

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

6.5 Nature and contents of container

Betnovate Scalp Application is supplied in polyethylene bottles and nozzles with caps of 30 ml and 100 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline (Ireland) Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1077/001/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 05 March 2009

10 DATE OF REVISION OF THE TEXT

September 2022