Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Betnovate Scalp Application 0.1 % w/w Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Betamethasone Valerate equivalent to 0.1% w/w Betamethasone

For full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous solution.

Imported from Greece

A colourless, hazy slightly viscous liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Betamethasone valerate 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

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 even less frequently.

4.3 Contraindications

Use in the presence of untreated infections of bacterial, viral, tuberculous or fungal origin.
Hypersensitivity to the preparation.
Dermatoses in children under one year of age, including dermatitis and napkin eruptions.
Use in acne vulgaris, rosacea or in perioral dermatoses.

4.4 Special warnings and precautions for use

Prolonged use of uninterrupted occlusion (including napkin) or use with extensive occlusive dressings may suppress adrenocortical function.

Continuous treatment for longer than three weeks on use of occlusion (including napkins) should be avoided in patients under the age of three years because of the possibility of adrenocortical suppression or of growth suppression, systemic absorption and hypercorticism.

Care must be taken to keep the preparation away from the eyes.
Do not use near a naked flame.

Betnovate preparations are usually well tolerated, but if signs of hypersensitivity appear, application should stop immediately. Exacerbation of symptoms may occur.

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 tolerances, 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 corticosteroids therapy and systemic administration of antibacterial 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.

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.

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

4.6 Fertility, pregnancy and lactation

Topical corticosteroids have induced teratogenic effects in animals. Similar effects have not been conclusively demonstrated with use during pregnancy in human beings. However, this product should not be used in pregnancy or lactation unless considered essential by the physician and only for the shortest period possible.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable 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.

<u>Immune system disorders</u>
Very rare: *Hypersensitivity.

If signs of *hypersensitivity appear, application should stop immediately.

<u>Endocrine disorders</u>
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. In infants, the napkin may act as an occlusive dressing.

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 corticosteroid (or its withdrawal) is thought to have provoked the pustular form of the disease.

4.9 Overdose

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Betamethasone Valerate is an active corticosteroid with topical anti-inflammatory activity.

5.2 Pharmacokinetic properties

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.
Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systematically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily by the liver and are then excreted by the kidneys.

5.3 Preclinical safety data

No additional data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Isoproyl Alcohol
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not known

6.3 Shelf life

The shelf life expiry date of this product shown on the bottle label and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C
Store in the original package

6.5 Nature and contents of container

Betnovate Scalp Application is supplied in 50ml bottles with nozzles in an over-labelled carton.

6.6 Special precautions for disposal and other handling

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

G&A Licensing Limited
Ballymurray
Co.Roscommon
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1447/059/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd December 2009

10 DATE OF REVISION OF THE TEXT