Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Betacap Scalp Application 0.1 % w/w cutaneous solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

0.1% w/w Betamethasone (as betamethasone valerate)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution.

Transparent, slightly gelled emollient scalp application.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of steroid-responsive dermatoses of the scalp, such as psoriasis and seborrhoeic dermatitis.

4.2 Posology and method of administration

For adults, including the elderly, and children over the age of one year, Betacap Scalp Application should be applied sparingly 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 the treatment of seborrhoeic dermatitis in children, the product should not be used for longer than 7 days.

4.3 Contraindications

Not to be used where there is bacterial, fungal or viral infection of the scalp.

Not to be used in cases of sensitivity to any of the ingredients.

Not to be used in children under the age of one year.

4.4 Special warnings and precautions for use

Keep away from the eyes.
Betacap is highly flammable. Do not use near a fire or naked flame. Allow the treated scalp to dry naturally.
Paediatric Population
Continuous long-term treatment should be avoided where possible, particularly in infants and children, as adrenal suppression can occur even without occlusion.
Use in Psoriasis
Complications sometimes associated with the use of topical corticosteroids in psoriasis include the possibility of rebound relapses, development of tolerance, 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.
Infection risk
Development of secondary infection requires withdrawal of topical corticosteroid therapy and commencement of appropriate systemic antimicrobial therapy
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.
Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advice is recommended in these cases or other treatment options should be considered.

For external use only.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Betamethasone valerate preparations are usually well tolerated, but if signs of hypersensitivity appear, application should be stopped immediately.
As with other topical corticosteroids, prolonged use of large amounts or treatment of extensive areas can result in sufficient systemic absorption to produce the features of hypercorticism and suppression of the HPA axis. These effects are more likely to occur in infants and children, and if occlusive dressings are used. Local atrophy may occur after prolonged treatment, particularly under occlusion.
In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.
Adverse drug reactions 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), very rare (<1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reaction
Immune System Disorders	Not known	Hypersensitivity
Endocrine Disorders	Not known	Hypothalamic-pituitary adrenal (HPA) axis suppression Hypercorticism
Skin and Subcutaneous Tissue Disorders	Not known	Skin atrophy Pustular psoriasis Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)
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

Acute overdosage is very unlikely to occur. However, in the case of chronic overdosage or misuse, the features of hypercorticism may appear and in this situation treatment with Betacap Scalp Application should be discontinued.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: D07AC - Corticosteroids, potent (group III)
ATC code: D07AC01

Betamethasone (as valerate) is a well-established example of a corticosteroid which is used in dermatological therapy in pharmacological doses for its anti-inflammatory and immuno-suppressive glucocorticoid properties. It suppresses the clinical manifestations of a wide range of inflammatory dermatoses and is frequently used at the concentration of 0.1% (as valerate).

5.2 Pharmacokinetic properties

Betacap Scalp Application comprises a slightly thickened evaporative alcoholic solution. It includes a coconut-oil related emollient ingredient to reduce the drying effect that a standard alcoholic vehicle may otherwise have on the scalp. The vehicle also contains isopropyl alcohol, which has antiseptic activity. The viscosity of the preparation has been adjusted so that it spreads easily to allow drug availability over the affected area, but is, however, viscous enough to avoid spreading onto uninvolved skin. The squeeze bottle and nozzle also allow easy application direct to the scalp through the hair.

After rapidly drying, the drug substance is deposited uniformly in a micronised crystalline form for efficient absorption into the skin. The lipid characteristics of the drug substance ensure that these micro-fine crystals rapidly dissolve in skin lipids to enhance molecular diffusion through the outer epidermal tissue and to enhance permeation into the deeper layers where it reverses the pathological processes responsible for the inflammatory dermatosis.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in this SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 7 glycerol cocoate
Isopropyl alcohol
Carbopol 980
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep in the original container.

6.5 Nature and contents of container

100 ml polyethylene squeeze bottle with integral nozzle/applicator and tamper-evident replaceable over-cap.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Dermal Laboratories (Ireland) Limited
38 Main Street
Swords
Co Dublin
K67 E0A2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23128/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 October 1993

Date of last renewal: 11 October 2008

10 DATE OF REVISION OF THE TEXT

November 2021