Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bettamousse 1mg/g (0.1%) cutaneous foam

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of foam contains 1 mg of betamethasone (0.1 %) as valerate.

Excipients with known effect:
Cetyl Alcohol 1.1% w/w
Stearyl Alcohol 0.5% w/w
Propylene Glycol (E1520) 2.0% w/w
Ethanol 57.79% w/w

For the full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous foam

White, foam mousse.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Bettamousse is indicated for steroid responsive dermatoses of the scalp, such as psoriasis.

4.2 Posology and method of administration

Posology

Adults, the elderly and children (over the age of six years):

No more than a "golf-ball" sized amount of mousse (containing approximately 3.5mg betamethasone), or proportionately less for children twice daily (in the morning and evening) until the condition improves. If there is no improvement after 7 days, treatment should be discontinued. Once the condition has improved, application is reduced to once a day and after daily treatment it may be possible to maintain improvement by applying even less frequently.

Paediatric population
In children over the age of 6 years, this product should not, in general, be used for longer than 5 to 7 days.

Method of administration
For topical use.

Shake the can well before use. Remove the cap, invert the can and dispense required amount of mousse onto a clean saucer or something similar. Dispensing directly onto hands should be avoided as the mousse will begin to melt when it touches skin. Massage sparingly into the affected areas of the scalp. Wash hands immediately after use. Do not wash hair immediately after use, allow the mouse to work overnight or through the day.

4.3 Contraindications

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

Bacterial, fungal, parasitic or viral infections of the scalp unless simultaneous treatment is initiated.

Dermatoses in children under six years of age.

4.4 Special warnings and precautions for use

Avoid contact with the eyes, open wounds and mucosae. Do not use near a naked flame.

The least amount of mousse required to control the disease should be used for the shortest possible time. This should minimise the potential for long term side effects. This is particularly the case in children, as adrenal suppression can occur even without its use with an occlusive dressing.

As with other topical corticosteroids, at least monthly clinical review is recommended if treatment is prolonged, and it may be advisable to monitor for signs of systemic activity.

The use of topical corticosteroids in psoriasis requires careful supervision. Glucocorticoids can mask, activate and worsen a skin infection. Development of secondary infection requires appropriate antimicrobial therapy and may necessitate withdrawal of topical corticosteroid therapy. Occlusive treatment should be avoided when there are signs of secondary infection. There is a risk of the development of generalised pustular psoriasis or local or systemic toxicity due to impaired barrier function of the skin.

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 advise is recommended in these cases or other treatment options should be considered.

Excipients
This medicine contains stearyl alcohol and cetyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

This medicine contains 2022 mg alcohol (ethanol) in each "golf-ball" sized amount of mousse (approx. 3.5g), which is equivalent to 57.79% w/w. It may cause burning sensation on damaged skin. Do not use near an open flame, lit cigarette or some devices (e.g. hairdryers).

This medicine contains 70mg of propylene glycol in each "golf-ball" sized amount of mousse (approx. 3.5g) which is equivalent to 2% w/w.

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 is no or limited data from the use of betamethasone valerate in pregnant women. Bettamousse should only be used in pregnancy if the potential benefit outweighs the risk. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development such as cleft palate, but the relevance of this in man is unknown. Reduced placental and birth weight have been recorded in animals and man after long-term treatment.

Breast-feeding
Bettamousse should only be used in lactation if the potential benefit outweighs the risk.

Betamethasone valerate are excreted in maternal milk, a risk of therapeutic doses having an effect on new borns/infants cannot be excluded.

Fertility
None

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The following side effects can occur with topical use of steroids.
They are ranked under headings of frequency using the following convention:

[Very Common (≥1/10); Common (≥1/100 to <1/10); Uncommon (≥1/1,000 to <1/100); Rare (≥1/10,000 to <1/1,000); Very Rare (<1/10,000)]; Frequency not known (cannot be estimated from the available data)

System Organ Class	Frequency	Adverse Events
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
Eye disorders	Not known	Vision, blurred (see also section 4.4)
Skin and subcutaneous 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*
	Not Known	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)
General disorders and administration site conditions	Very rare	Application site irritation/pain

If signs of hypersensitivity appear, application should be stopped immediately.

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. In this situation topical steroids should be discontinued under careful clinical supervision, with supportive therapy if appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic (ATC) code: DO7AC: Corticosteroids, dermatological preparations, potent (group III).

Betamethasone valerate is a glucocorticosteroid which has topical anti-inflammatory activity.

5.2 Pharmacokinetic properties

Under conditions of normal use, topical administration of betamethasone valerate is not associated with clinically significant systemic absorption.

5.3 Preclinical safety data

Topical administration of corticosteroids to pregnant animals has been associated with abnormalities of foetal development and growth retardation, although the relevance of this in humans is unknown.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetylalcohol
Stearyl alcohol
Polysorbate 60
Ethanol anhydrous
Purified Water
Propylene glycol E1520
Citric acid anhydrous
Potassium Citrate
Butane/Propane

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25^{o}C. Do not refrigerate.

6.5 Nature and contents of container

Pressurised container.

Aluminium EP (epoxy phenolic) lined cebal can with precision valve and clear cover cap, with a net weight of 50g or 100g.

Not all pack sizes may be marketed.

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

RPH Pharmaceuticals AB
Box 603
101 32 Stockholm
Sweden

8 MARKETING AUTHORISATION NUMBER

PA1638/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 November 1998

Date of last renewal: 13 November 2008

10 DATE OF REVISION OF THE TEXT

October 2022