

## **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 betamethasone (0.1 %) as valerate

#### Excipients with known effect:

Cetyl Alcohol 1.10 % w/w

Stearyl alcohol 0.50 % w/w

Propylene glycol (E1520) 2.00 % w/w

Ethanol anhydrous 57.79% w/w

For the full list of excipients, see section 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.

Note: for proper dispensing of foam, the container should be held upside down and the actuator depressed.

The patient or carer should 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. The product is to be massaged sparingly into the affected areas of the scalp. It is recommended to wash hands immediately after use. Hair should not be washed immediately after use, allowing the mousse 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.

Tolerance may develop and rebound relapse may occur on withdrawal of treatment. 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. 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.

### Excipients

This medicine contains cetyl alcohol and stearyl 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 70 mg 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.

Breastfeeding

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

Betamethasone valerate is 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**

Bettamousse has no known influence on the ability to drive and use machines.

**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 ( $\geq 1/10$ ); Common ( $\geq 1/100$  to  $< 1/10$ ); Uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); Rare ( $\geq 1/10,000$  to  $< 1/1,000$ ); Very Rare ( $< 1/10,000$ ); Frequency not known (cannot be estimated from the available data)

<b>System Organ Class</b>	<b>Frequency</b>	<b>Adverse Events</b>
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 the Yellow Card Scheme at

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### **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 fetal development and growth retardation, although the relevance of this in humans is unknown.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Cetyl alcohol  
Stearyl alcohol  
Polysorbate 60  
Ethanol anhydrous  
Purified Water

Propylene glycol (E1520)  
Citric acid anhydrous  
Potassium Citrate  
Butane/Propane

## **6.2 Incompatibilities**

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

## **6.3 Shelf life**

2 years.

## **6.4 Special precautions for storage**

Do not store above 25°C. Do not refrigerate. Store upright.

## **6.5 *Nature and contents of container***

Pressurised container.

Aluminium EP-lined Cebal can with Precision valve and clear cover cap, with a net weight of 50 or 100g.

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal**

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

RPH Pharmaceuticals AB  
Box 603  
101 32 Stockholm  
Sweden

**8     MARKETING AUTHORISATION NUMBER(S)**

PL 36301/0036

**9     DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

19 April 1996/19 April 2001

**10    DATE OF REVISION OF THE TEXT**

13/10/2022