Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bettamousse 1 mg/g (0.1% w/w) Cutaneous Foam

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of foam contains 1 mg betamethasone (as valerate) equivalent to 0.1% w/w betamethasone.

Excipients: Cetyl alcohol
Stearyl alcohol
Propylene glycol (E1520)

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous foam
Product imported from Italy:
White, foam mousse

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Steroid responsive dermatoses of the scalp, such as psoriasis.

4.2 Posology and method of administration

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, to be massaged into the affected areas of the scalp 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. In children over the age of 6 years, this product should not, in general, be used for longer than 5 to 7 days.
Patients should be advised to use the product sparingly.

4.3 Contraindications

Bacterial, fungal, parasitic or viral infections of the scalp unless simultaneous treatment is initiated.
Hypersensitivity to any component of the preparation.
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.
Tolerance may develop and rebound relapse may occur on withdrawal of treatment.

Some of the excipients (Stearyl alcohol, cetyl alcohol or propylene glycol) may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

Not relevant to topical use.

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Bettamousse should only be used in pregnancy or lactation 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.
While betamethasone valerate passes over into the maternal milk, there appears to be little risk of therapeutic doses having an effect on the baby.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

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 hypothalamic-pituitary-adrenal axis. These effects are more likely to occur in children, and if occlusive dressings are used.
Individual cases of headache, stinging and pruritus have been described. If signs of hypersensitivity appear, application should be stopped immediately.
The following side effects can occur with topical use of steroids:
Less common: 1/100-1/1000. Skin atrophy, stria distensae. Secondary infection. Rosacea-like dermatitis (face). Ecchymoses.
Rare: <1/1000. Hypertrichosis. Hypersensitivity (steroid). Hypo-/hyper-pigmentation. Folliculitis. Telangiectases.
Other side effects include: purpura, acne (especially during prolonged application). Rarely, perioral dermatitis and systemic activity.
In rare instances, treatment of psoriasis with corticosteroids (or their withdrawal) is thought to have provoked the pustular form of the disease. (See Precautions).

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 is a glucocorticosteroid which has topical anti-inflammatory activity.

5.2 Pharmacokinetic properties

Under conditions of normal use, topical administration of betamethasone 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

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

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate.
The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C.
Do not pierce the canister.

6.5 Nature and contents of container

Pressurised container.
Aluminium EP (epoxy-phenolic) lined cabal can with precision valve and clear cover cap, with a net weight of 100g.

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 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1328/72/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 12 January 2012

10 DATE OF REVISION OF THE TEXT

February 2012