

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone 1mg/g (0.1% w/w) as valerate

Excipients contains:

Cetyl alcohol 1.1% w/w

Stearyl alcohol 0.5% w/w

Propylene glycol 2.0% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous foam

Product imported from Italy:

Appearance: White, foam mousse

4 CLINICAL PARTICULARS

As per PA 1638/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 1638/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetyl alcohol

Stearyl alcohol

Polysorbate 60

Ethanol

Purified Water

Propylene glycol

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.

6.5 Nature and contents of container

Pressurised container

Aluminium can with clear cover cap, with a net weight of 100g.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/209/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 22nd February 2008

10 DATE OF REVISION OF THE TEXT

October 2015