

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Elocon 0.1% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mometasone Furoate 0.1% w/w (equivalent to 1.0mg/g)
Excipient: includes propylene glycol stearate and stearyl alcohol
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
Product imported from the Spain
White to off white smooth homogenous cream

4 CLINICAL PARTICULARS

As per PA1286/035/001.

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/035/001.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hexylene glycol
Phosphoric acid
Propylene glycol stearate
Stearyl alcohol and cetareth-20
Titanium dioxide
Aluminium starch octenylsuccinate
White beeswax
White soft paraffin
Purified Water

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.

6.5 Nature and contents of container

Overlabelled cardboard carton containing on overlabelled aluminium tube with cap. Pack size : 1 x 30g tube

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

B & S Healthcare
Unit 4 Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/127/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th January 2010

10 DATE OF REVISION OF THE TEXT

March 2015