

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 with known effect: hydrogenated soya phosphatidylcholine

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from Spain.

A white to off-white 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,
Hydrogenated soya phosphatidylcholine,
Titanium dioxide,
Aluminium starch octenylsuccinate,
White wax,
White petrolatum,
Phosphoric acid,
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the tube 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

30 g aluminium tube with a screw cap.

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

PPA1562/145/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th December 2015

10 DATE OF REVISION OF THE TEXT