

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Elocon 0.1% w/w Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mometasone Furoate 0.1% w/w (equivalent to 1.0 mg/g)

Excipient with known effect:

This medicine contains 20.0 mg propylene glycol stearate in each gram of the ointment which is equivalent to 600.0 mg propylene glycol stearate per unit (30g tube).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment

Product imported from Spain:

A white to off-white, opaque ointment.

4 CLINICAL PARTICULARS

As per PA23198/010/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/010/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

hexylene glycol
white beeswax
propylene glycol stearate
white petrolatum
purified water
phosphoric acid (pH adjustment).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

Use within one month after opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

30 g aluminium tubes

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/239/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th March 2025

10 DATE OF REVISION OF THE TEXT