Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dermovate 0.05 % w/w Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains 0.5 mg of clobetasol propionate (equivalent to 0.05% w/w).

Excipients with known effect:
Propylene glycol

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ointment

Product imported from Romania

A white to off-white, translucent, homogeneous ointment.

4 CLINICAL PARTICULARS

As per PA1077/005/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/005/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Sorbitan sesquioleate
White soft paraffin

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

Store below 30°C in the original packaging.

6.5 Nature and contents of container

Dermovate Ointment is supplied in 4 x 25g collapsible aluminium tubes.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Patients should be advised to wash their hands after applying Dermovate, unless it is the hands that are being treated.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th April 2017

10 DATE OF REVISION OF THE TEXT

February 2022