# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Dermovate Scalp Application 0.05% w/v cutaneous solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml of cutaneous solution contains 5 mg of clobetasol propionate (equivalent to 0.05% w/v).

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cutaneous solution

*Product imported from Greece*

A colourless, clear to slightly hazy, slightly viscous solution.

## 4 CLINICAL PARTICULARS

As per PA1077/005/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/005/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

carbomer
isopropyl alcohol
sodium hydroxide (for pH adjustment)
water purified

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the bottle 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. Keep container tightly closed when not in use. Contents are flammable. Keep away from fire, flame or heat. Do not leave clobetasol propionate scalp application in direct sunlight.

**6.5 Nature and contents of container**

2 squeeze bottles each with an elongate nozzle containing 50ml of a colourless, clear to slightly hazy, slight viscous liquid.

Pack size 2 x 50ml.

**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**

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**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23176/005/002

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 21st July 2017

**10 DATE OF REVISION OF THE TEXT**

November 2023