

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Dermovate Scalp Application 0.05% w/v Cutaneous Solution

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clobetasol propionate 0.05% w/w.

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Cutaneous solution

*Product imported from Portugal*

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

Isopropyl Alcohol  
Carbomer 980 NF  
Sodium Hydroxide  
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 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.

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**

A plastic bottle with an elongate nozzle containing a colourless, clear to slightly hazy, slightly viscous liquid.

Pack size: 100 ml

## **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**

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

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

LTT Pharma Limited  
Unit 18  
Oxleasow Road  
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United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1562/093/001

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

Date of first authorisation: 7<sup>th</sup> December 2012

## **10 DATE OF REVISION OF THE TEXT**

September 2016