

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Differin 0.1% w/w Gel

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Adapalene 0.1% w/w

Excipient(s) with known effect

Propylene Glycol (E1520)

Methyl Parahydroxybenzoate (E218)

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Gel.

*Product imported from France*

A white gel.

## 4 CLINICAL PARTICULARS

As per PA0590/006/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0590/006/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carbomer 980

Propylene glycol

Poloxamer 182

Sodium edetate

Methyl parahydroxybenzoate (E218)

Phenoxyethanol

Sodium hydroxide and/or Hydrochloric acid

Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product is the date shown on the tube and outer carton of the product as marked in the country of origin.

## **6.4 Special precautions for storage**

Do not store above 25°C.  
Do not freeze.

## **6.5 Nature and contents of container**

Cardboard outer containing a tube  
Pack size: 30g

## **6.6 Special precautions for disposal and other handling**

No special requirements.

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

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/198/002

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

Date of first authorisation: 15<sup>th</sup> May 2015

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

May 2018