

# 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 smooth white gel.

## 4 CLINICAL PARTICULARS

As per PA 22743/005/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA 22743/005/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carbomer 980

Propylene glycol (E1520)

Poloxamer 182

Disodium edetate

Methyl parahydroxybenzoate (E218)

Phenoxyethanol

Sodium hydroxide or hydrochloric acid

Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container 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.

Do not freeze.

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

White tube with white screw cap.

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**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/437/001

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

October 2017

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

October 2019