

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Differin 0.1% w/w cream

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Adapalene 0.1% w/w

Excipient(s) with known effect:

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate (E216)

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cream

*Product imported from France*

White cream

## 4 CLINICAL PARTICULARS

As per PA22743/005/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA22743/005/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carbomer 934P

PEG-20 methyl glucose sesquistearate

Glycerol

Natural Squalane

Methyl Parahydroxybenzoate (E218)

Propyl Parahydroxybenzoate (E216)

Disodium edetate

Methyl glucose sesquistearate

Phenoxyethanol

Cyclomethicone

Sodium Hydroxide solution 10 per cent

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 tube and outer packaging of the product as marketed 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**

Tube with a white screw cap.

Pack size: 30 g

#### **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**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

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

PPA1463/120/001

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

Date of first authorisation: 1<sup>st</sup> February 2019

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

October 2022