

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 shiny 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 974P

Polyoxyethyleneglycol 1000 methyl glucose sesquistearate

Glycerol (E422)

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 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

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/437/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th December 2017

10 DATE OF REVISION OF THE TEXT

September 2019