

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

White gel

4 CLINICAL PARTICULARS

As per PA22743/005/002

5 PHARMACOLOGICAL PROPERTIES

As per PA22743/005/002

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 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

White tube with 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

PPA1463/120/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st February 2019

10 DATE OF REVISION OF THE TEXT

October 2022