

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 PA0590/006/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0590/006/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer 980

Propylene glycol (E1520)

Poloxamer 182

Sodium 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 on the tube 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 LDPE tube with white PP screw cap.
Pack sizes: 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

LTT Pharma Limited
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/136/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 9th January 2015

10 DATE OF REVISION OF THE TEXT

May 2018