

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dovonex 50 micrograms/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 50 micrograms of calcipotriol (as the hydrate).
Excipients include Cetostearyl alcohol

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
Product imported from Italy.
Soft, white cream.

4 CLINICAL PARTICULARS

As per PA0046/061/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0046/061/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether
Cetostearyl alcohol
Chloroallylhexaminium chloride
Disodium edetate
Disodium phosphate dihydrate
Glycerol 85%
Liquid paraffin
White soft paraffin
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.
Use within 6 months after first opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Lacquered aluminium tube with polyethylene screw cap.
Pack size: 30 g.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
Unit 4
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United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/023/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th October 2006

Date of last renewal: 13th October 2011

10 DATE OF REVISION OF THE TEXT

November 2015