

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dovobet 50 microgram/g + 0.5 mg/g Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of ointment contains 50 micrograms of calcipotriol (as monohydrate), and 0.5 mg of betametasone (as dipropionate).

Excipient with known effect: butylhydroxytoluene (E321).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment

Product imported from Italy:
Off-white to yellow ointment.

4 CLINICAL PARTICULARS

As per PA 1025/001/001.

5 PHARMACOLOGICAL PROPERTIES

As per PA 1025/001/001.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

liquid paraffin
polyoxypropylene-15-stearyl ether
all-rac-alpha-tocopherol
white soft paraffin
butylhydroxytoluene (E321)

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

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.

After first opening of container: 1 year

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

The product is presented in a tube with a screw cap contained in an over-labelled carton.
Tube sizes: 30g and 120 g.

Not all pack sizes may be marketed.

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
Bradfield Road
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HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/066/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 5th January 2007

Date of Last Renewal: 5th January 2012

10 DATE OF REVISION OF THE TEXT

February 2016