Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dovobet 50 microgram/g + 0.5 mg/g gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of gel contains 50 micrograms of calcipotriol (as monohydrate) and 0.5 mg of betamethasone (as dipropionate).

Excipient with known effects:
Butylhydroxytoluene (E321) 160micrograms/g gel

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.
An almost clear, colourless to slightly off-white gel.

4 CLINICAL PARTICULARS

As per PA1025/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1025/001/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin, liquid
Polyoxypropylene-15 stearyl ether
Castor oil, hydrogenated
Butylhydroxytoluene (E321)
α-tocopherol

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: 3 months.

6.4 Special precautions for storage

Do not refrigerate. Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

High-density polyethylene bottles with a low-density polyethylene nozzle and a high-density polyethylene screw cap. The bottles are placed in cartons.
Pack sizes: 30 grams

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
Unit 4, Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/066/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th September 2014

10 DATE OF REVISION OF THE TEXT

January 2016