

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 effect:
Butylhydroxytoluene (E321)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.

Product imported from Norway, the UK and Greece:
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 stearyl ether
Castor oil, hydrogenated
Butylhydroxytoluene (E321)
All-rac- 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

Unopened container: The shelf life expiry date of this product is the date shown on the container and outer carton of the product as marketed 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: 60 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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/213/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th July 2012

10 DATE OF REVISION OF THE TEXT

March 2017