

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dovobet 50 microgram/g + 0.5 mg/g ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment

Product imported from the UK:
Off-white to yellow.

4 CLINICAL PARTICULARS

As per PA1025/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1025/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Liquid paraffin
- Polyoxypropylene stearyl ether
- All-rac- α -tocopherol
- White soft paraffin
- Butylhydroxytoluene (E321)

6.2 Incompatibilities

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

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer package of the product on the market in the country of origin.

Shelf life after first opening is 1 year.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium/epoxyphenol tubes with polyethylene screw cap in an over labelled outer container

Tube size: 120g

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

iMed Healthcare Ltd.
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Northwest Business Park
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/022/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th May 2009

10 DATE OF REVISION OF THE TEXT

May 2016