

## 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- $\alpha$ -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 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.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/022/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 8<sup>th</sup> May 2009

## **10 DATE OF REVISION OF THE TEXT**

May 2016