

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Canesten HC Cream
Clotrimazole 1.0%w/w
Hydrocortisone 1.0%w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The cream contains 1% w/w of clotrimazole and 1% w/w of hydrocortisone.
Also contains cetostearyl alcohol.

For a full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from the UK
A white to pale-yellow cream.

4 CLINICAL PARTICULARS

As per PA1410/040/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/040/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Cetostearyl alcohol
Medium chain triglycerides
Triceteareth-4 phosphate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C. Store in the original carton.

6.5 Nature and contents of container

Aluminium tube with internal lacquer coating and HDPE screw-on cap in an over-labelled cardboard carton.

Pack size: 30 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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/049/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd September 2011

10 DATE OF REVISION OF THE TEXT

August 2015