

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Canesten Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains clotrimazole 1% w/w (equivalent to 10mg/g).
Excipients with known effect: cetostearyl alcohol.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from the United Kingdom

A white oil-in-water type cream.

4 CLINICAL PARTICULARS

As per PA1410/039/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/039/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Polysorbate 60
Sorbitan Stearate
Cetyl Palmitate
Cetostearyl alcohol
Octyldodecanol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the tube and outer package 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 package.

6.5 Nature and contents of container

Tubes with screw on caps containing 20 g cream. Each tube is contained within a cardboard carton.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/191/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th November 2016

10 DATE OF REVISION OF THE TEXT