

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Canesten 10 mg/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 10 mg clotrimazole equivalent to 1% w/w.

Excipient(s) with known effect: cetostearyl alcohol and benzyl alcohol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

Product imported from Greece and Portugal

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

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date on the container and outer package of the product in the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/048/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 April 2000

Date of last renewal: 14 April 2010

10 DATE OF REVISION OF THE TEXT

August 2022