

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Canesten Thrush Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 20mg clotrimazole (2% w/w)

Excipient with known effect: Cetostearyl alcohol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Vaginal Cream

Product imported from Spain

A white oil-in water type cream

4 CLINICAL PARTICULARS

As per PA1410/039/012

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/039/012

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 of this product is the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions

6.5 Nature and contents of container

Tube (20g) with a screw top.

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

Imbat Ltd,
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/201/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th October 2016

10 DATE OF REVISION OF THE TEXT