

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Canesten 500 mg Pessary.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pessary contains 500mg clotrimazole. For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pessary.

Product imported from the UK and Greece:

White, convex pessary marked 'BAYER' on one side and 'MU' on the other.

4 CLINICAL PARTICULARS

As per PA1410/039/009

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/039/009

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

Microcrystalline cellulose

Lactic acid

Maize starch

Crospovidone

Calcium lactate pentahydrate

Magnesium stearate

Silica, colloidal anhydrous

Hypromellose

Product sourced from Greece also contain 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

Do not store above 25 °C.

6.5 Nature and contents of container

Each pessary is packed into a foil blister. The foil blister is enclosed in an over-labelled outer cardboard carton with a disposable applicator and patient information leaflet.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/048/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03 March 2006

Last updated: February 2021

10 DATE OF REVISION OF THE TEXT

April 2022