

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Canesten Combi Pessary & Cream

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The pessary contains clotrimazole 500 mg.

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

Excipient(s) with known effect: Cetostearyl alcohol

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Pessary and vaginal cream

*Product imported from UK:*

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

A white oil-in-water type cream

## 4 CLINICAL PARTICULARS

As per PA1410/039/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1410/039/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Pessary:

Lactose monohydrate

Microcrystalline cellulose

Lactic acid

Maize starch

Crospovidone

Calcium lactate pentahydrate

Magnesium stearate

Silica, colloidal anhydrous

Hypromellose

#### Cream:

Sorbitan stearate

Cetyl Palmitate

Cetostearyl alcohol

Octyldodecanol

Benzyl alcohol

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 blister consisting of 25 micrometers PA/45 micrometers soft aluminium/ 60 micrometers PVC and 20 micrometers hard aluminium/7g/m<sup>2</sup> heat seal lacquer. The cream is supplied in overlabelled aluminium tubes. Both components are enclosed in an overlabelled 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**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/048/003

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorization: 25<sup>th</sup> June 2009

Last updated: April 2011

Last updated: March 2014

Last updated: March 2015

## **10 DATE OF REVISION OF THE TEXT**

November 2020