

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Canesten Thrush Cream

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients with known effect: cetostearyl alcohol, benzyl alcohol

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Vaginal Cream

*Product imported from Greece*

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

sorbitan monostearate

polysorbate 60

cetylates ester wax

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 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

Aluminium tubes (20g) with a stopper and a screw top.

## **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**

IMED Healthcare Ltd,  
Unit 625 Kilshane Avenue,  
Northwest Business Park,  
Ballycoolin,  
Dublin 15,  
Ireland.

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/226/001

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

Date of first authorisation: 31<sup>st</sup> May 2024

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