

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).

Excipients with known effect:

Cetostearyl alcohol 100mg in each gram of cream

Benzyl alcohol 20mg in each gram of cream

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

Sorbitan stearate

Polysorbate 60

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 container¹ and outer carton of the product as marketed 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 (20 g) 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

Lexon Pharmaceuticals (Ireland) Limited
Block 3,
Harcourt Centre,
Harcourt Road,
Dublin 2,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/061/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th May 2023

10 DATE OF REVISION OF THE TEXT