Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamisil 250 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains terbinafine hydrochloride equivalent to 250 mg terbinafine.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Product imported from the Czech Republic and Portugal
Circular, biconvex white tablets with 'LAMISIL 250' on one side and a breakline on the other.
The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

As per PA0896/015/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/015/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Hypromellose
Microcrystalline cellulose
Sodium starch glycolate
Colloidal anhydrous silica

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.
Keep the blisters in the outer carton in order to protect from light.

6.5 Nature and contents of container

Blister packs containing 14 or 28 tablets contained in an outer cardboard carton.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/096/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 April 2003

Date of last renewal: 17 April 2008

10 DATE OF REVISION OF THE TEXT

May 2023