Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamisil 1% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 10 mg terbinafine hydrochloride (1% w/w).

Excipient(s) with known effect: Contains cetyl alcohol and stearyl alcohol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

Product imported from Greece and Spain:
White, smooth, glossy cream.

4 CLINICAL PARTICULARS

As per PA0678/121/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0678/121/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide
Benzyl alcohol
Sorbitan stearate
Cetyl palmitate
Cetyl alcohol
Stearyl alcohol
Polysorbate 60
Isopropyl myristate
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 30 °C.

6.5 Nature and contents of container

Aluminium or laminate tube of 15 g and 30 g cream contained in an outer cardboard carton.
Not all pack sizes may be marketed.

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

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

PPA0465/151/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02 December 2005

Date of last renewal: 01 December 2010

10 DATE OF REVISION OF THE TEXT

January 2024