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).

Excipients with known effects: Contains cetyl alcohol, stearyl alcohol and benzyl alcohol

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

Product imported from France.
White, smooth to almost smooth, glossy cream.

4 CLINICAL PARTICULARS

As per PA22650/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22650/009/001

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

This medication comes in the form of a 15g tube of cream contained in an outer 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

No special 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

PPA1463/192/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th July 2022

10 DATE OF REVISION OF THE TEXT

May 2024