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
Circular, biconvex, bevelled-edge, white or off-white tablets about 11mm in diameter. One face is scored and the reverse is marked 'Lamisil 250'. 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 glycollate (Type A)
Silica colloidal anhydrous

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

6.5 Nature and contents of container

PVC/PVDC blister packs containing 14 or 28 tablets.
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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/157/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th February 2021

10 DATE OF REVISION OF THE TEXT