Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamisil 250mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains terbinafine hydrochloride equivalent to 250mg terbinafine.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
Product imported from Greece & Spain:
Round, white tablet that is scored on one side and printed ‘LAMISIL 250’ on the reverse.

4 CLINICAL PARTICULARS

As per PA0013/045/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0013/045/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Hypromellose
Microcrystalline cellulose
Sodium starch glycolate
Silica colloidal anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be 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

Product imported from Spain:
Do not store above 30°C.
Keep blisters in the outer carton to protect from light.

Product imported from Greece:
Do not store above 25ºC.
Keep blisters in the outer carton to protect from light.

6.5 Nature and contents of container

Calendar blister packs in a cardboard carton, containing 28 tablets.

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

Imbat Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/029/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 8th June 2007

Date of Last Renewal: 8th June 2012

10 DATE OF REVISION OF THE TEXT

August 2017