

# 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 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

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.,  
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Dublin 15,  
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/192/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 15<sup>th</sup> July 2022

**10 DATE OF REVISION OF THE TEXT**