

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lamictal 100 mg tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 100 mg tablet contains 100 mg lamotrigine.

Excipient with known effect: Each tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from Greece and Bulgaria and Czech Republic:*

Pale, yellowish-brown, multifaceted, super-elliptical tablet, marked "GSEE5" on one side and "100" on the other.

## 4 CLINICAL PARTICULARS

As per PA1077/061/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose monohydrate  
Microcrystalline cellulose  
Povidone K30  
Sodium starch glycolate (Type A)  
Iron oxide yellow (E172)  
Magnesium stearate.

### 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

This medicinal product does not require any special storage conditions.

## **6.5 Nature and contents of container**

Carton containing PVC/aluminium blister strips.

Pack size of 56 or 60 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 for disposal.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/066/005

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

Date of First Authorisation: 4<sup>th</sup> July 2014

## **10 DATE OF REVISION OF THE TEXT**

August 2024