

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lamictal 200 mg tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 200 mg tablet contains 200 mg lamotrigine.

Excipient(s) with known effect: lactose.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from Greece:*

Pale, yellowish-brown, multifaceted, super-elliptical tablets, marked "GSEE7" on one side and 200 on the other.

## 4 CLINICAL PARTICULARS

As per PA1077/061/004

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/004

## 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 blister 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

*Product imported from Greece*

Blisters of 60 tablets

Not all pack sizes may be marketed.

#### **6.6 Special precautions for disposal**

No special requirements for disposal.

#### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

#### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/092/013

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

Date of first authorisation: 20<sup>th</sup> February 2015

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

June 2024