# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lamictal 50 mg chewable/dispersible tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 50 mg chewable/dispersible tablet contains 50 mg lamotrigine.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Chewable/dispersible tablet.

*Product imported from Spain and Germany*
White to off-white square tablet with rounded corners with a blackcurrant odour, marked "GSCX7" on one side and "50" on the other. The tablets may be slightly mottled.

## 4 CLINICAL PARTICULARS

As per PA1077/061/008

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/008

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Calcium carbonate
Low-substituted hydroxypropyl cellulose
Aluminium magnesium silicate
Sodium starch glycolate (Type A)
Povidone K30
Saccharin sodium
Magnesium stearate
Blackcurrant flavour

### 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 carton of the product as marketed 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

Blister packs of 56 chewable/dispersible tablets.

**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**

PPA0465/443/002

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

Date of first authorisation: 14th September 2012
Last updated: April 2016
Last updated: September 2018
Last updated: May 2019

**10 DATE OF REVISION OF THE TEXT**

April 2023