

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lamictal 25 mg chewable/dispersible tablets.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 25 mg chewable/dispersible tablets contains 25 mg lamotrigine.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Chewable/dispersible tablet.

*Product imported from Spain:*

White to off-white square tablet with rounded corners with a blackcurrant odour, marked “GSCL5” on one side “25” on the other. The tablets may be slightly mottled.

## 4 CLINICAL PARTICULARS

As per PA 1077/061/007

## 5 PHARMACOLOGICAL PROPERTIES

As per PA 1077/061/007

## 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 contained in an overlabelled outer carton.

## **6.6 Special precautions for disposal**

No special requirements for disposal.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

WPR Healthcare Limited  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA 0565/050/001

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

Date of first authorisation: 14<sup>th</sup> September 2012

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

April 2016