

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lamictal 50 mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 50 mg tablet contains 50 mg lamotrigine.

Excipient with known effect: lactose.  
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.  
*Product imported from Romania:*  
Pale, yellowish-brown, multifaceted, super-elliptical tablet, marked “GSEE1” on one side and “50” on the other.

## 4 CLINICAL PARTICULARS

As per PA1077/061/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/002

## 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**

PVC/aluminium foil blister. Packs of 28 tablets.

## **6.6 Special precautions for disposal and other handling**

No special requirements for disposal.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Primecrown 2010 Limited  
4/5 Northolt Trading Estate  
Belvue Road  
Northolt  
Middlesex  
UB5 5QS  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1633/041/002

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

Date of first authorisation: 3<sup>rd</sup> November 2014

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

July 2017