

# 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: Each tablet contains lactose.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from Portugal 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**

Each pack contains 56 tablets.

## **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.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/092/010

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

Date of first authorisation: 31st May 2013

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

April 2015