

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lamictal 200mg tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 200mg tablet contains 200mg lamotrigine.  
Excipient: Each tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet

*Product imported from the UK*  
Pale yellowish-brown, square tablets with rounded corners, 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 is the date shown on the blister 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**

Over-labeled outer carton containing blister strips.  
Pack size: 56

## **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 MARKETING AUTHORISATION HOLDER**

GlaxoSmithKline (Ireland) Limited  
Stonemasons Way  
Rathfarnham  
Dublin 16  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/115/009

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

Date of first authorisation: 24<sup>th</sup> January 2014

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

October 2014