

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Lamictal 100mg chewable/dispersible tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 100mg chewable/dispersible tablet contains 100mg lamotrigine.

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Chewable/dispersible tablet.

*Product imported from Greece:*

White, square tablets with rounded corners with 'Lamictal 100' on one side.

*Product imported from the Netherlands:*

White, square tablets with rounded corners with '100' on one side and 'GSCL7' on the other.

### 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  
Hyprolose  
Aluminium magnesium silicate  
Sodium starch glycolate  
Povidone K 30  
Saccharin Sodium  
Magnesium stearate  
Blackcurrant flavouring

#### 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 package of the product on the market in the country of origin.

#### **6.4 Special precautions for storage**

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

#### **6.5 Nature and contents of container**

Blister packs containing 30 or 90 tablets in an over labelled outer carton.

Not all pack sizes may be marketed.

#### **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**

PPA0465/092/007

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

Date of first authorisation: 11 July 2003

Date of last renewal: 11 July 2008

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

November 2016