

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lamictal 50mg Dispersible Chewable Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 50 mg dispersible/chewable tablet contains 50 mg lamotrigine.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Dispersible/chewable tablet

*Product imported from Italy:*

White to off-white multi-faceted, super-elliptical, tablet with a blackcurrant odour, marked “GSCX7” on one side and “50” on the other. The tablets may be slightly mottled.

## 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  
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 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**

Over-labelled carton containing 4 blister strips (14 tablets per strip).  
Pack size of 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**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/066/001

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

Date of first authorisation: 3<sup>rd</sup> August 2012

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

September 2014