

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lamictal 50 mg chewable/dispersible tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 50 mg chewable/dispersible tablet contains 50 mg lamotrigine.  
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Chewable/dispersible tablet.

*Product imported from Germany*

White to off-white multi-faceted, super-elliptical, tablets 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  
Hyprolose  
Aluminium magnesium silicate  
Poly(O-carboxymethyl) starch, sodium salt  
Povidone K30  
Sodium saccharine  
Magnesium stearate (Ph. Eur.)  
Blackcurrant flavour

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister 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

Blister packs of 56 tablets.

## **6.6 Special precautions for disposal**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Unit 18, Oxleasow Road  
East Moons Moat  
Redditch  
Worcestershire  
B98 0RE  
United Kingdom

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Lexon Pharmaceuticals (Ireland) Limited  
Block 3  
Harcourt Centre  
Harcourt Road  
Dublin 2  
Ireland

## **8 MARKETING AUTHORISATION NUMBER**

PPA1097/007/004

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23176/003/004

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

Date of first authorisation: 19<sup>th</sup> May 2017

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

October 2021