

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lamictal 200 mg chewable/dispersible tablets.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 200 mg chewable/dispersible tablet contains 200 mg lamotrigine.

For a 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, tablet with a blackcurrant odour, marked "GSEC5" on one side and "200" on the other. The tablets may be slightly mottled.

## 4 CLINICAL PARTICULARS

As per PA1077/061/010

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/010

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Calcium carbonate  
Hyprolose  
Aluminium magnesium silicate  
Poly (O-carboxymethyl) starch, sodium salt  
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 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

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**

PPA1463/066/003

**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**

April 2022