

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Lamictal 25 mg Dispersible Chewable Tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 25mg dispersible chewable tablet contains 25mg lamotrigine.

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Dispersible/chewable tablet.

*Product imported from Spain:*

White to off-white square tablet with rounded corners with a blackcurrant odour, marked "GSCL5" on one side "25" on the other. The tablets may be slightly mottled.

### 4 CLINICAL PARTICULARS

As per PA1077/061/007

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/007

### 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 shall be 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

This medicinal product does not require any special storage conditions.

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

PVC/PVdC/aluminium foil blister packs of 14 tablets per blister in an outer carton.  
Pack size of 56 dispersible/chewable tablets.

## **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

B & S Healthcare  
Unit 4, Bradfield Road  
Ruislip  
Middlesex, HA4 0NU  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1328/128/002

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

Date of first authorisation: 30<sup>th</sup> November 2012

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

March 2016