

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lamictal 200 mg Dispersible Chewable Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Dispersible/chewable tablet

*Product imported from Italy:*

Lamictal tablets are white to off-white, with a blackcurrant odour, and may be slightly mottled. They are square with rounded edges, engraved with ‘GSEC5’ on one side; and ‘200’ on the other side.

## 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  
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**

White plastic and foil blister pack of 14 tablets per blister in an overlabelled 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**

PPA1328/128/003

## **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