

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 200mg chewable/dispersible tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable/dispersible tablet

Product imported from Italy:

White, rounded-square tablets branded with '200' on one side and 'GSEC5' on the other.

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
- Blackcurrant flavour
- Magnesium stearate

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 package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Blister packs of 56 Dispersible 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

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/092/009

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th March 2007

Date of last renewal: 16th March 2012

10 DATE OF REVISION OF THE TEXT

November 2016