Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 25 mg chewable/dispersible tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable/dispersible tablet.

Product imported from Spain and Germany:
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 is the date shown on the container and outer carton of the product as marketed 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 chewable/dispersible tablets.

6.6 Special precautions for disposal

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/443/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th September 2012
Last updated: April 2016
Last updated: September 2018
Last updated: May 2019

10 DATE OF REVISION OF THE TEXT

May 2023