Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 5 mg chewable/dispersible tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 5 mg chewable/dispersible tablet contains 5 mg of lamotrigine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable/dispersible tablet

Product imported from Greece and Spain:
White to off-white, elongated, biconvex tablets with a blackcurrant odour, marked '5' on one side and 'GSCL2' on the other. The tablets may be slightly mottled.

4 CLINICAL PARTICULARS

As per PA1077/061/006

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/006

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate
Low-substituted hydroxproylcellulose
Aluminium magnesium silicate
Sodium starch glycolate
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

Blister: Do not store above 25 °C. Store in the original package in order to protect from light and moisture.
Bottle: This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister packs containing 30 tablets in an overlabelled outer carton or 28 tablets in a carton.

Product imported from Spain: HDPE bottle containing 60 tablets with a child resistant/tamper evident closure.

Not all pack sizes may be marketed.

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.

6.6 Special precautions for disposal

No special requirements.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/092/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th July 2003

Date of last renewal: 11th July 2008

10 DATE OF REVISION OF THE TEXT

May 2020