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 Germany

White to off-white tablets of 5.2 mm 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
Povidone K30
Saccharin sodium
Magnesium Stearate (Ph. Eur)
Blackcurrant flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister 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

Blister packs of 56 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th February 2017

10 DATE OF REVISION OF THE TEXT

October 2021