Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 50 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 50 mg tablet contains 50 mg lamotrigine.
Excipient: Each tablet contains lactose.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
Product imported from Czech Republic
Pale, yellowish-brown, tablets of 7.4 mm marked "GSEE1" on one side and 50 on the other.

4 CLINICAL PARTICULARS

As per PA1077/061/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Povidone K30
Sodium starch glycolate (Type A)
Iron oxide yellow (E172)
Magnesium stearate

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 for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/003/002

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