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(s) with known effect
Lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK, Czech Republic and Greece
Pale, yellowish-brown, multifaceted, super-elliptical tablet, 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 of this product shall be 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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Product imported from UK and Czech Republic
PVC/Aluminium foil blister. Each pack contains 56 tablets.

Product imported from Greece
Blisters of 60 tablets.

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

6.6 Special precautions for disposal

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/092/012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09th May 2014

10 DATE OF REVISION OF THE TEXT

December 2018