Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 50mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 50mg tablet contains 50mg lamotrigine.
Excipient: Each tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from the UK
Pale, yellowish-brown, square tablets with rounded corners, 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 is the date shown on the blister strips 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

Over-labeled outer carton containing blister strips.
Pack size: 56

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.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Ltd,
Unit L2,
North Ring Business Park,
Santry,
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/115/007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th January 2014

10 DATE OF REVISION OF THE TEXT

October 2014