Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 50 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg 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, 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
Sodium starch glycolate (Type A)
Povidone K30
Magnesium stearate
Iron oxide yellow (E172)

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

Over-labelled carton containing 4 PVC/aluminium blister strips (14 tablets per strip).
Pack size of 56 tablets.

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

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moon Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/011/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th August 2009

Date of last renewal: 14th August 2014

10 DATE OF REVISION OF THE TEXT

June 2015