

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 100 mg Dispersible/Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 100mg dispersible/chewable tablet contains 100mg lamotrigine.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Dispersible/chewable tablet.

Product imported from Italy and Germany:

White to off-white multi-faceted, super-elliptical, tablet with a blackcurrant odour,marked “GSCL7” on one side and “100” on the other. The tablets may be slightly mottled.

4 CLINICAL PARTICULARS

PA1077/061/009

5 PHARMACOLOGICAL PROPERTIES

PA1077/061/009

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Italy:

- Calcium carbonate
- Low-substituted hydroxypropyl cellulose
- Aluminium magnesium silicate
- Sodium starch glycolate (Type A)
- Povidone K30
- Saccharin sodium
- Magnesium stearate
- Blackcurrant flavour

Product imported from Germany:

- Calcium carbonate
- Hyprolose
- Aluminium magnesium silicate
- Sodium starch glycollate
- Sodium chloride
- Povidone K30
- Saccharin sodium
- Magnesium stearate
- Blackcurrant flavour

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 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

Product imported from Italy: Over-labelled outer carton containing blister strips.

Product imported from Germany: Aluminium blisters in a re-box outer carton.

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/115/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th March 2011

10 DATE OF REVISION OF THE TEXT

January 2015