

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 25mg dispersible/chewable tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 25mg dispersible/chewable tablet contains 25mg lamotrigine.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Dispersible/chewable tablet

Product imported from Germany and Italy:

White to off-white multi-faceted, super-elliptical tablet with a blackcurrant odour marked 'GSCL5' on one side and '25' on the other.

4 CLINICAL PARTICULARS

As per PA1077/061/007

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/007

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Germany:

Calcium carbonate
hydroxypropyl cellulose
Aluminium magnesium silicate
Sodium starch glycolate
Povidone K30
Saccharin sodium
Magnesium stearate
Blackcurrant flavour

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

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister strip 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

Cardboard outer containing blister strips.

Pack size: 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/115/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st August 2009

10 DATE OF REVISION OF THE TEXT

January 2015