

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 50mg Dispersible/Chewable Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 50mg dispersible/chewable tablet contains 50mg lamotrigine.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Dispersible/chewable tablet.

Product imported from Italy

The tablets are white to off-white, multi-faceted, super-elliptical, with a blackcurrant odour, marked “GSCX7” on one side and “50” on the other. The tablets may be slightly mottled.

4 CLINICAL PARTICULARS

As per PA1077/061/008

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/61/008

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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 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

Over-labelled 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 Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/115/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th February 2011

10 DATE OF REVISION OF THE TEXT

January 2015