Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 50 mg chewable/dispersible tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 50 mg chewable/dispersible tablet contains 50 mg lamotrigine.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable/dispersible tablet

Product imported from Germany:

White to off-white multi-faceted, super-elliptical, tablet 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 PA1077/061/008

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate
Hyprolose
Aluminium magnesium silicate
Poly (O-carboxymethyl) starch, sodium salt
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 blister 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

Carton containing 4 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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/066/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd August 2012

10 DATE OF REVISION OF THE TEXT

April 2022