

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 100mg Dispersible Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Dispersible/chewable tablet

Product imported from Italy:

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

As per PA1077/061/009

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/009

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 is the date shown on the container and outer carton 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 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.
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Northwest Business Park
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1463/066/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd August 2012

10 DATE OF REVISION OF THE TEXT

September 2014