Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 50 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 50 mg tablet contains 50 mg lamotrigine.

Excipient with known effect: Each tablet contains lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from *Bulgaria, Greece, Slovakia and Croatia:*
Pale, yellowish-brown, multifaceted, super-elliptical tablets of 7.4 mm marked "GSEE1" on one side and 50 on the other.

4 CLINICAL PARTICULARS

As per PA1077/061/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Povidone K30
Sodium starch glycolate (Type A)
Iron oxide yellow (E172)
Magnesium stearate

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 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

Bulgarian, Slovakian and Croatian sourced pack:
Packs of 56 tablets.

Greece sourced pack:
Packs of 60 tablets

PVC/aluminium foil blister.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/066/008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd April 2021

10 DATE OF REVISION OF THE TEXT

November 2025