Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 25 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 25 mg tablet contains 25 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 and Croatia:
Pale, yellowish-brown, multifaceted, super-elliptical tablet, marked "GSEC7" on one side and "25" on the other.

4 CLINICAL PARTICULARS

As per PA1077/061/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/001

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

Over-labelled carton containing 4 PVC/aluminium 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 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

PPA1463/066/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 4th July 2014

10 DATE OF REVISION OF THE TEXT

November 2025