

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: lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from Romania:

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

PVC/aluminium foil blister. Packs of 28 tablets.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Merit Pharmaceuticals Limited
Unit C4 Metropoint Business Park
Kettles Lane
Swords
Co Dublin
K67 RH92
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23080/014/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd November 2014

10 DATE OF REVISION OF THE TEXT

May 2021