Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 100 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 mg lamotrigine.

Excipient(s) 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 Portugal and Czech Republic
Pale, yellowish-brown, multifaceted, super-elliptical tablets of 9.4 mm marked "GSEE5" on one side and 100 on the other.

4 CLINICAL PARTICULARS

As per PA1077/061/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/003

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 for 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

PVC/aluminium foil blister. Packs of 56 tablets.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.,
Joop Geesinkweg 901,
1114 AB Amsterdam-Duivendrecht,
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/024/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th August 2022

10 DATE OF REVISION OF THE TEXT