

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 200 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 200 mg tablet contains 200 mg lamotrigine.

Excipient: Each tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK

Pale, yellowish-brown, multifaceted, super-elliptical tablet, marked “GSEE7” on one side and “200” on the other.

4 CLINICAL PARTICULARS

As per PA1077/061/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/004

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

Overlabelled carton containing 4 PVC/aluminium blister strips (14 tablets per strip).
Packs 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

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/011/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd August 2012

10 DATE OF REVISION OF THE TEXT

June 2016