Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 25mg chewable/dispersible tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 25mg chewable/dispersible tablet contains 25 mg of lamotrigine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable/dispersible tablet.

Product imported from Greece:
White, square tablets with rounded corners with ‘Lamictal 25’ on one side.

Product imported from the Netherlands:
White, square tablets with rounded corners with ‘25’ on one side and ‘GSCL5’ on the other.

4 CLINICAL PARTICULARS

As per PA1077/061/007

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/007

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate
Hyprolose
Aluminium magnesium silicate
Sodium starch glycolate
Povidone K 30
Saccharin Sodium
Magnesium stearate
Blackcurrant flavouring

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Blister packs containing 30 or 42 tablets in an over labelled outer container.

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

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/092/006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th July 2003

Date of last renewal: 11th July 2008

10 DATE OF REVISION OF THE TEXT

November 2016