Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamictal 50mg chewable/dispersible tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lamictal 50mg chewable/dispersible tablet contains 50mg lamotrigine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable/dispersible tablet

Product imported from The Netherlands:
White, rounded-square tablets with a blackcurrant odour, branded ‘GSCX7’ on one side and ‘50’ on the other.

4 CLINICAL PARTICULARS

As per PA1077/061/009

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/061/009

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate
Low substituted hydroxypropyl cellulose
Aluminium magnesium silicate
Sodium starch glycolate (Type A)
Povidone K30
Saccharin sodium
Blackcurrant flavour
Magnesium stearate

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 of 90 Dispersible 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/092/008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th March 2007

Date of last renewal: 16th March 2012

10 DATE OF REVISION OF THE TEXT

November 2016