Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

TOPAMAX 100mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 100 mg of topiramate.

Excipient(s) with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.
Product imported from Spain
Yellow, round tablet, 9 mm in diameter, marked ‘TOP’ on one side and ‘100’ on the other.

4 CLINICAL PARTICULARS

As per PA0748/012/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0748/012/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core tablet:
Lactose monohydrate
Pregelatinised maize starch
Microcrystalline cellulose
Sodium starch glycolate (Type A)
Magnesium stearate

Film-coating:
OPADRY Yellow[1]
Carnauba Wax

[1]OPADRY contains:
Hypromellose
Macrogol
Polysorbate 80
Titanium dioxide (E171)
Iron oxide yellow (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25^{o}C. Store the tablets in the original package to protect from moisture.

6.5 Nature and contents of container

Blister pack of an aluminium/aluminium foil in strips. Pack sizes of 60 tablets.

6.6 Special precautions for disposal

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

PPA1562/111/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th June 2014

10 DATE OF REVISION OF THE TEXT

January 2017