Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Topamax 25 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 25 mg of topiramate.

Excipients with known effect: also includes lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Romania & Spain
White, round tablet marked ‘TOP’ on one side and ‘25’ on the other.

4 CLINICAL PARTICULARS

PA0748/012/001

5 PHARMACOLOGICAL PROPERTIES

PA0748/012/001

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 White[1]
Carnauba Wax

[1]OPADRY contains:
Hypromellose
Macrogol
Polysorbate 80
Titanium dioxide (E171)

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

Over-labelled outer carton containing blister strips.
Pack size: 60 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

Imbat Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/209/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st February 2014

10 DATE OF REVISION OF THE TEXT

November 2017