Summary of Product Characteristics

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1 NAME OF THE MEDICINAL PRODUCT

Topamax 25mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 25 mg, of topiramate.

Excipients with known effects: also includes lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Spain, the Netherlands, Lithuania, Greece and Poland:
White round tablets, 6 mm in diameter ,'TOP' on one side and '25' on the other.

4 CLINICAL PARTICULARS

As per PA22612/013/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22612/013/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

Film-coating:
OPADRY White[1]
Carnauba Wax

[1]OPADRY White contains:
Hypromellose
Macrogol
Polysorbate 80
And as colourant, titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be 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 the tablets in the original package (blister or bottle) to protectfrom moisture. Keep the bottle tightly closed to protect the tablets frommoisture.

6.5 Nature and contents of container

Available in opaque plastic bottle with tamper-evident closure containing 56 or 60 tablets: bundle pack comprising 56 (2 x28) tablets or in 6 blister strips in an outer cardboard carton. In each bottle there is a desiccant canister which should not be swallowed.
Pack size of 56 or 60 tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/196/001

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

October 2024