

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Topamax 50 mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 50 mg, of topiramate.

Excipients with known effect: also includes lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet

Product imported from Spain, Lithuania and Greece

Light yellow, embossed, round tablets imprinted with "TOP" on one side and "50" on the other.

4 CLINICAL PARTICULARS

As per PA22612/013/002

5 PHARMACOLOGICAL PROPERTIES

As per PA22612/013/002

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 Yellow¹

Carnauba Wax

OPADRY Yellow contains:

Hypromellose

Macrogol

Polysorbate 80

And as colorants, titanium dioxide (E171) and Yellow iron oxide (E172)

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 protect from moisture. Keep the bottle tightly closed to protect the tablets from moisture.

6.5 Nature and contents of container

Available in opaque containers with tamper evident closures containing 60 tablets, or in six blisters in an outer cardboard carton. In each bottle there is a desiccant canister which should not be swallowed.

Pack size of 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

PPA0465/196/002

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

September 2022