

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Topamax 200 mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 200 mg 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 France, Spain, The Netherlands, Lithuania and Greece:

Salmon, embossed, round tablets imprinted with "TOP" on one side and "200" on the other.

4 CLINICAL PARTICULARS

As per PA22612/013/004

5 PHARMACOLOGICAL PROPERTIES

As per PA22612/013/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core

Lactosemonohydrate
Pregelatinised Maize starch
Microcrystallinecellulose
Sodium starch glycolate (Type A)
Magnesium stearate

Film coating

OPADRY Pink¹
Carnauba wax

¹Opadry Pink contains:

Hypromellose
Macrogol
Polysorbate80

And as colorants, Titanium dioxide (E171) and
Red 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

Blister packs containing 28 or 60 tablets or opaque plastic containers with tamper-evident closures containing 60 tablets. In each bottle there is a desiccant canister which should not be swallowed.

Not all pack sizes may be marketed.

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/196/004

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

May 2019