

# 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 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, Greece and Poland:*  
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 Pink<sup>1</sup>  
Carnauba wax

<sup>1</sup>Opadry Pink contains:

Hypromellose  
Macrogol  
Polysorbate80  
And as colorants, Titanium dioxide (E171) and  
Red iron oxide (E172)

### 6.2 Incompatibilities

Not applicable  
30 October 2024



### **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 bottle with tamper-evident closures containing 56 or 60 tablets: bundle pack comprising 56 (2 x28) 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: 16<sup>th</sup> March 2007

Date of last renewal: 16<sup>th</sup> March 2012

## **10 DATE OF REVISION OF THE TEXT**

October 2024