# 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 of topiramate.

Excipient with known effect
Lactose monohydrate

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film coated tablet
*Product imported from Netherlands and Lithuania*
Salmon-coloured, round tablets, 10 mm in diameter, "TOP" on one side, "200" on the other side.

## 4 CLINICAL PARTICULARS

As per PA22612/013/004

## 5 PHARMACOLOGICAL PROPERTIES

As per PA22612/013/004

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Core tablet
Lactose monohydrate
Pregelatinised maize starch
Microcrystralline cellulose (E460)
Sodium starch glycolate (Type A)
Magnesium stearate

Film-coating
OPADRY Pink[1]
Carnauba wax
[1]OPADRY Pink contains
Hypromellose (E464)
Macrogol
Polysorbate 80
Titanium dioxide (E171)
Iron oxide red (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 blister 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 in the original package in order to protect from moisture.

**6.5 Nature and contents of container**

Blister packs containing 60 tablets.

**6.6 Special precautions for disposal**

No special requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Originalis B.V.
Joop Geesinkweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA2306/003/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 15th February 2019

**10 DATE OF REVISION OF THE TEXT**

December 2020