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 100 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 100 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 Lithuania
Yellow, round tablets, 9 mm in diameter, "TOP" on one side and "100" on the other.

4 CLINICAL PARTICULARS

As per PA22612/013/003

5 PHARMACOLOGICAL PROPERTIES

As per PA22612/013/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core tablet:
Lactose Monohydrate
Pregelatinised Maize Starch
Microcrystalline Cellulose
Sodium Starch Glycolate (Type A)
Magnesium Stearate

Film-coating:
OPADRY® Yellow[1]
Carnauba Wax

[1]OPADRY® Yellow contains:
Hypromellose
Macrogol
Polysorbate 80
And as colourants, titanium dioxide E171 and iron oxide yellow E172

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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 pack of an aluminium/aluminium foil in strips. Pack sizes of 60 tablets.
Individual (alu/alu) blister strips are packed inside a folding box.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.
Diamantweg 4
1812 RC Alkmaar
The Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/003/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th December 2025

10 DATE OF REVISION OF THE TEXT

August 2026