Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Topamax 25 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 25 mg of topiramate.

Excipients with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from *Greece*
White, round tablets, 6 mm in diameter, "TOP" on one side and "25" on the other.

4 CLINICAL PARTICULARS

As per PA22612/013/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22612/013/001

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 White[1]
Carnauba Wax

[1]OPADRY White contains:
Hypromellose
Macrogol
Polysorbate 80
Titanium dioxide (E171)

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 in the original package and keep the bottle tightly closed in order to protect from moisture.

6.5 Nature and contents of container

Opaque plastic bottle with tamper-evident closure containing 60 tablets. In each bottle there is a desiccant canister which should not be swallowed.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/136/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th April 2021

10 DATE OF REVISION OF THE TEXT

June 2022