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 50 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 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 Portugal
Light yellow, round tablet marked 'TOP' on one side and '50' on the other.

4 CLINICAL PARTICULARS

As per PA22612/013/002

5 PHARMACOLOGICAL PROPERTIES

As per PA22612/013/002

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
Titanium dioxide (E171)
Iron oxide yellow (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister and outer carton of the product as marketed 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

Over-labelled outer carton containing blister strips.
Pack size: 60 tablets

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

PPA1463/136/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st February 2014

10 DATE OF REVISION OF THE TEXT

August 2024