

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Topamax 50mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 50 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 Slovakia
Description of the product
Light yellow, round tablets, 7 mm in diameter, “TOP” on one side and “50” on the other.

4 CLINICAL PARTICULARS

As per PA0748/012/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0748/012/002

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 Yellow1
Carnauba Wax
1OPADRY 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 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 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

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

PPA1463/106/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th March 2016

10 DATE OF REVISION OF THE TEXT