

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 Greece
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
microcrystalline cellulose
sodium starch glycolate
pregelatinized starch
magnesium Stearate

Film-coating:
carnauba wax
OPADRY Light Yellow which contains:
titanium dioxide E171
hypromellose
macrogol
polysorbate 80
yellow iron oxide (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 bottle 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 (bottle) to protect from moisture. Keep the bottle tightly closed to protect the tablets 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 and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon (UK) Ltd
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd December 2016

10 DATE OF REVISION OF THE TEXT