Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Topamax 100 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 100 mg of topiramate.

Excipient 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 Portugal and Greece
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

Product imported from Portugal
Core tablet:
Lactose monohydrate
Pregelatinized maize starch
Microcrystalline cellulose
(Sodium) carboxymethyl starch (Type A)
Magnesium Stearate

Film-coating:
Opadry white
Opadry yellow
Opadry Pink
Carnauba wax

[1]OPADRY contains hypromellose, macrogol, polysorbate 80 and contains titanium dioxide E171, Iron oxide yellow E172

Product imported from Greece
Core tablet:
Lactose Monohydrate
Pregelatinized 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
As a colourant, 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 packaging of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25 °C.
Bottle: Store in the original package and keep the bottle tightly closed to protect the tablets from moisture.
Blister: Store the tablets in the original package (blister) to protect from moisture.

6.5 Nature and contents of container

Blister pack of aluminium/aluminium foil in strips. Pack sizes of 60 tablets.
or
Opaque plastic bottle with tamper-evident closure containing 60 tablets. In each bottle there is a desiccant canister which should not be swallowed.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th July 2017

10 DATE OF REVISION OF THE TEXT

October 2021