Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

TOPAMAX 100 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 mg of topiramate.

Excipient(s) with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Products imported from Greece.

Yellow, round tablets, 9 mm in diameter, "TOP" on one side and "100" on the other.

4 CLINICAL PARTICULARS

As per PA 22612/013/003.

5 PHARMACOLOGICAL PROPERTIES

As per PA22612/013/003

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 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 of this product is the date shown on the outer package 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 and 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

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3, Harcourt Centre,
Harcourt Road,
Dublin 2,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first autorisation: 12th August 2022

10 DATE OF REVISION OF THE TEXT