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 the end of section 4 of the package leaflet for how to report side effects.

1 NAME OF THE MEDICINAL PRODUCT

Topamax 50 mg 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 Portugal
Light yellow, round tablets, 7 mm in diameter, "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
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.
Blisters: Store 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 size of 60 tablets. Individual (alu/alu) blister strips are packed inside a folding box.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Merit Pharmaceuticals Limited
Unit C4/C3
Metropoint Business Park
Kettles Lane
Swords
Co Dublin
K67 RH92
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23080/016/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd September 2006

Date of last renewal: 22nd September 2011

10 DATE OF REVISION OF THE TEXT

September 2024