Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Topamax 25 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 25 mg of topiramate

Excipient with known effect
Lactose (as monohydrate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Portugal
White, round tablets, 6 mm in diameter, "TOP" on one side and "25" on the other.

4 CLINICAL PARTICULARS

As per PA22612/013/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22612/013/001

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 White[1]
Carnauba wax

[1]OPADRY White contains:
Hypromellose
Macrogol
Polysorbate 80
and as colourants titanium Dioxide E171

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 in the original package in order to protect from moisture.

6.5 Nature and contents of container

Aluminium blister packs of 60 tablets.

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

PPA23080/016/001

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

January 2023