

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Topamax 50 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 50 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

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 Yellow¹

Carnauba Wax

¹OPADRY 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. 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
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Metropoint Business Park
Kettles Lane
Swords
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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

January 2023