

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Topamax 50mg Film-coated Tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 50 mg of topiramate.

Excipients: 62 mg lactose monohydrate

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Film-coated tablets

*Product imported from Spain:*

Light yellow, round tablets, 7mm in diameter, "TOP" on one side and "50" on the other.

### 4 CLINICAL PARTICULARS

PA0748/012/002

### 5 PHARMACOLOGICAL PROPERTIES

PA0748/012/002

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

*Core Tablet:*

Lactose Monohydrate  
Pregelatinized Starch  
Microcrystalline Cellulose  
Sodium Starch Glycolate (Type A)  
Magnesium Stearate

*Film-coating:*

Hypromellose  
Polyethylene glycol  
Polysorbate 80  
Titanium Dioxide (E171)  
Iron Oxide (E172)  
Carnauba wax

## **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 packaging 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**

Blister strips of 10 tablets in an overlabelled cardboard carton  
Pack size: 60 tablets.

## **6.6 Special precautions for disposal**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Clear Pharmacy  
157-173 Roden Street  
Belfast BT12 5QA  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1596/058/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 9<sup>th</sup> December 2011

## **10 DATE OF REVISION OF THE TEXT**

June 2015