

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Trileptal 300 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 300 mg of oxcarbazepine.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablets.

*Product imported from Spain, Greece, Bulgaria and Poland;*

Yellow, ovaloid tablets, scored on both sides. Embossed with TE/TE on one side and CG/CG on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

## 4 CLINICAL PARTICULARS

As per PA0896/033/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0896/033/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Tablet core:

Silica, colloidal anhydrous

Cellulose, microcrystalline

Hypromellose

Crospovidone

Magnesium stearate

#### Tablet coating:

Hypromellose

Talc

Titanium dioxide (E171)

Macrogol 8000

Iron oxide, yellow (E172)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer carton of the product on the market in the country of origin.

#### **6.4 Special precautions for storage**

Store below 30 °C.

#### **6.5 Nature and contents of container**

Blister containing 10 tablets. Blister pack of 50 tablets.

#### **6.6 Special precautions for disposal**

No special requirements.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/308/001

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

Last updated: March 2013  
Last updated: June 2014  
Last updated: December 2014  
Last updated: January 2015  
Last updated: November 2016

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

August 2023