

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Trileptal 60 mg/ml oral suspension.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of the oral suspension contains 60 mg oxcarbazepine.

Excipient(s) with known effect: Each ml also contains propylparahydroxybenzoate (E216), methylparahydroxybenzoate (E218), sorbitol ( E 420) 70 % liquid (non crystallising), ethanol and propylene glycol (E 1520).

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral suspension.

*Product imported from Greece*

Off-white to slightly reddish brown oral suspension.

## 4 CLINICAL PARTICULARS

As per PA0896/033/004

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0896/033/004

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Propyl parahydroxybenzoate (E 216)  
Saccharin sodium  
Sorbic acid (E 200)  
Macrogol stearate 400  
Methyl parahydroxybenzoate (E 218)  
Yellow-plum-lemon flavour (containing ethanol)  
Ascorbic acid (E 300)  
Dispersible cellulose (containing microcrystalline cellulose and carmellose sodium)  
Propylene glycol (E 1520)  
Sorbitol (E 420) 70% liquid (non-crystallising)  
Water purified.

### 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.

Use within 7 weeks after first opening the bottle.

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

This medicinal product does not require any special storage conditions.

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

An overlabelled brown (amber) glass bottles containing 250 ml of oral suspension. The bottle has a child-resistant cap and is packed in an overlabelled cardboard box together with a 10 ml polypropylene oral syringe and press-in bottle adaptor. Pack size: 1 bottle

#### **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**

PPA0465/308/003

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

Date of first authorisation: 22<sup>nd</sup> July 2016

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

May 2021