# 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: propyl parahydroxybenzoate (E216), methyl parahydroxybenzoate (E218), sorbitol liquid (non-crystallising) and ethanol.

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 (E216)
Saccharin sodium
Sorbic acid (E200)
Macrogol stearate 400
Methyl parahydroxybenzoate (E218)
Yellow-plum-lemon flavour (containing ethanol)
Ascorbic acid (E300)
Dispersible cellulose (containing microcrystalline cellulose and carmellose sodium)
Propylene glycol
Sorbitol 70% liquid (non-crystallising)
Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the bottle 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**

Brown (amber) glass bottles containing 250 ml of oral suspension. The bottles have a child-resistant cap and are packed in a cardboard box together with a 10 ml oral syringe and press-in bottle adapter.

Pack size: 1 bottle

**6.6 Special precautions for disposal**

No special requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23176/018/001

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

Date of first authorisation: 27th April 2018

**10 DATE OF REVISION OF THE TEXT**

November 2022