# 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 of oxcarbazepine.

Excipients with known effect:
Each ml contains 175 mg sorbitol (E420), 25 mg propylene glycol (E1520), propylparahydroxybenzoate (E216), methylparahydroxybenzoate (E218) and 0.8 mg ethanol.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral suspension.

Product imported from *Bulgaria;*
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 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**

Store below 25°C.

**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 adaptor.

Pack size: 1 bottle

**6.6 Special precautions for disposal**

No special requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.
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Ballycoolin
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Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/154/001

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

Date of first authorisation: 15th January 2021

**10 DATE OF REVISION OF THE TEXT**

March 2022