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: 22nd July 2016

10 DATE OF REVISION OF THE TEXT

August 2023