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), propylene glycol (E1520), sorbitol 70 % liquid (non crystallising) (E420) and 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 (E216);
Saccharin sodium;
Sorbic acid (E200);
Macrogol stearate 400;
Methyl parahydroxybenzoate (E218);
Yellow-plum-lemon flavour (containing ethanol);
Ascorbic acid (E300);
Dispersible cellulose
Propylene glycol (E1520);
Sorbitol 70% liquid (non-crystallising) (E420);
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 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

Do not store above 25°C.

6.5 Nature and contents of container

Brown (amber) glass bottle containing 250 ml of oral suspension. The bottle has 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

Originalis B.V.
Joop Geesinkweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st February 2019

10 DATE OF REVISION OF THE TEXT

April 2022