

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Trileptal 600 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 600 mg oxcarbazepine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

Product imported from Spain, Greece, Bulgaria and Belgium:

Light pink, ovaloid tablets scored on both sides. Embossed with TF/TF on one side and CG/CG on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA0896/033/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/033/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Silica, colloidal anhydrous
Cellulose, microcrystalline
Hypromellose
Crospovidone
Magnesium stearate

Tablet coating:

Hypromellose
Talc
Titanium dioxide (E171)
Macrogol 4000
Iron oxide red (E172)
Iron oxide black (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer carton of the product on the market in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister containing 10 tablets.
Blister pack of 50, tablets.
Not all pack sizes may be marketed.

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

PPA0465/308/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Last updated: March 2013
Last updated: June 2014
Last updated: December 2014
Last updated: January 2015
Last updated: November 2016

10 DATE OF REVISION OF THE TEXT

August 2024