

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Trileptal 300 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 300 mg of oxcarbazepine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

Product imported from Spain, Greece, Bulgaria, Poland and Belgium:

Yellow, ovaloid tablets, scored on both sides. Embossed with TE/TE 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 PA0896/033/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/033/002

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 8000

Iron oxide, yellow (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.

Storage conditions for Trileptal 300 mg film-coated tablets sourced from Poland: Store below 30 °C.

6.5 Nature and contents of container

Blister containing 10 tablets. Blister pack of 50 tablets.

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

PPA0465/308/001

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

October 2024