

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 *Bulgaria*

Yellow, ovaloid slightly biconvex 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 (E 171)
Macrogol 8000
Iron oxide, yellow (E 172)

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 package 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.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
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Northwest Business Park
Ballycoolin
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/154/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th January 2021

10 DATE OF REVISION OF THE TEXT