

# 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 oxcarbazepine.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*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  
Microcrystalline cellulose  
Hypromellose  
Crospovidone  
Magnesium stearate

Tablet coating:

Hypromellose  
Macrogol 8000  
Yellow iron oxide (172)  
Talc  
Titanium dioxide (E171)

### 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 pack of 50 tablets

#### **6.6 Special precautions for disposal**

No special requirements.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Lexon Pharmaceuticals (Ireland) Limited  
Block 3  
Harcourt Centre  
Harcourt Road  
Dublin 2  
Ireland

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23176/018/002

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 6<sup>th</sup> September 2019

### **10 DATE OF REVISION OF THE TEXT**

February 2022