

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Neurontin 800 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 800 mg gabapentin.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from Spain*

White, elliptical film-coated tablet with a bisecting score on both sides and debossed with 'NT' and '26' on one side.

The tablet can be divided into equal doses.

## 4 CLINICAL PARTICULARS

As per PA0822/015/005

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0822/015/005

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Poloxamer 407 (ethylene oxide and propylene oxide)

Copovidone

Maize starch

Magnesium stearate

*Film-coating*

Opadry white YS-1-18111 (hydroxypropylcellulose, talc)

*Polishing agent*

Candelilla wax

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of 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

Do not store above 25 °C.

#### **6.5 Nature and contents of container**

PVC/PE/PVDC/aluminium foil blister packs or PVC/PVDC/aluminium foil blister packs.  
Supplied in packs of 90 or 100 film-coated 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**

PPA0465/097/005

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

Date of first authorisation: 18<sup>th</sup> October 2019

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