Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Neurontin 100 mg hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100mg hard capsule contains 100mg of gabapentin

Excipients with known effect:
Each 100mg hard capsule contains lactose (as monohydrate).
For the full list of excipients, *see section 6.1*

3 PHARMACEUTICAL FORM

Capsule, hard

Product imported from France
Neurontin 100mg hard capsules: A two piece, white opaque hard gelatin capsule, imprinted with 'Neurontin 100mg' and 'PD' and containing a white to off-white powder.

Product imported from the UK
The 100mg capsules are white hard capsules marked with "Neurontin 100mg" and "PD".

4 CLINICAL PARTICULARS

As per PA0822/015/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/015/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents
Lactose monohydrate
Maize starch
Talc

Capsule shell
Gelatin
Sodium laurilsulfate
Titanium dioxide (E171)

Printing Ink
Shellac
Titanium dioxide (E171)
Indigo carmine (E132)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container 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

Blister pack containing 90 and 100 capsules in an outer cardboard carton.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

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

PPA0465/097/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 July 2005
Date of last renewal: 08 July 2010

10 DATE OF REVISION OF THE TEXT

January 2020