

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Neurontin 400 mg hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 400mg hard capsule contains 400mg of gabapentin

Excipients with known effect:

Each 400 mg hard capsule contains lactose (as monohydrate).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Capsule, hard

Product imported from Greece, UK & Spain

A two-piece, orange opaque hard gelatin capsule, imprinted with 'Neurontin 400mg' and the 'PD', containing a white to off-white powder.

4 CLINICAL PARTICULARS

As per PA0822/015/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/015/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Greece & UK

Lactose monohydrate

Maize starch

Talc

Gelatin

Titanium dioxide (E171)

Yellow iron oxide (E172)

Red iron oxide (E172)

The product imported from the UK also contains:

Sodium laurilsulfate

Shellac

Indigo carmine

Product imported from Spain

Lactose monohydrate

maize starch

Talc

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 50, 90 or 100 capsules in an outer cardboard carton.
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

PPA0465/097/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 January 2003
Date of last renewal: 24 January 2008

10 DATE OF REVISION OF THE TEXT

January 2020