

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Neurontin 600 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 600mg film-coated tablet contains 600mg of gabapentin.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablets

Product imported from UK & Spain:

White, elliptical film-coated tablets with a bisecting score on both sides and debossed with "NT" and "16" on one side. The tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA 0822/015/004

5 PHARMACOLOGICAL PROPERTIES

As per PA 0822/015/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Each film-coated tablet contains the following 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 for this product shall be 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

PVC/PE/PVDC/aluminium foil blister in overlabeled outer Cartons. Pack sizes 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

PPA0465/097/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th September 2009

10 DATE OF REVISION OF THE TEXT

January 2020