

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Neurontin 600 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from the UK

Film-coated tablet

Neurontin 600 mg film-coated tablets are 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 PA0822/015/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/015/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Film-coated tablets

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 of this product is the date shown on the container and outer carton 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 100 film coated tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/084/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th November 2013

10 DATE OF REVISION OF THE TEXT

March 2018