Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Neurontin 100 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mg hard capsule contains 100 mg of gabapentin.

Excipients:
Each 100 mg hard capsule contains lactose (as monohydrate).
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard

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

4 CLINICAL PARTICULARS

As per PA0822/015/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/015/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsules, hard

Each hard capsule contains the following excipients: lactose monohydrate, maize starch and talc.

Capsule shell: gelatin, purified water and sodium lauryl sulphate.

The 100 mg hard capsules contain the colouring E171 (titanium dioxide).

The printing ink used on all hard capsules contains shellac, E171 (titanium dioxide) and E132 (indigocarmine).

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 30°C

6.5 Nature and contents of container

PVC/PVDC/aluminium foil blister packs supplied in packs of 100 capsules.

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

PPA1463/084/001

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