

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Neurontin 300 mg hard capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 300 mg hard capsule contains 300 mg of gabapentin.

Excipient(s) with known effect

Lactose (as monohydrate).

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Capsule, hard.

*Product imported from the United Kingdom*

A two-piece, yellow opaque hard gelatin capsule, imprinted with 'Neurontin 300mg' and 'PD' and containing a white to off-white powder.

## 4 CLINICAL PARTICULARS

As per PA0822/015/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0822/015/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Capsule contents:

Lactose monohydrate

Maize starch

Talc

Capsule shell:

Gelatin

Purified water

Sodium laurilsulfate

Titanium dioxide (E171)

Yellow Iron Oxide (E172)

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 shall be the date shown on the blister strips and outer carton of the product as marked in the country of origin.

## 6.4 Special precautions for storage

Do not store above 30°C.

## 6.5 Nature and contents of container

Cardboard outer carton containing blister strips.  
Pack size: 100 hard capsules

## 6.6 Special precautions for disposal

No special requirements.

## 7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited  
Unit L2, North Ring Business Park  
Santry  
Dublin 9  
Ireland

## 8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/224/002

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13<sup>th</sup> June 2014

## 10 DATE OF REVISION OF THE TEXT

April 2018