Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sinemet CR 50mg/200 mg Prolonged-release Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet of Sinemet CR contains carbidopa (equivalent to 50 mg of anhydrous carbidopa) and 200 mg levodopa.

For the full list of excipients, *see section 6.1*.

3 PHARMACEUTICAL FORM

Prolonged-release tablets.

Product imported from Italy
Peach-coloured, oval-shaped, biconvex tablets, plain on one side, the other side scored and marked`521'.

The score line is not intended to facilitate breaking of the tablet.

4 CLINICAL PARTICULARS

As per PA1286/009/006.

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/009/006.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hyprolose
Magnesium stearate
Poly (vinyl acetate-crotonic acid) copolymer
Quinoline yellow aluminium hydrate
Red iron oxide E172

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 30°C.
Store in original package in order to protect from light.

6.5 Nature and contents of container

Blister packs of 60 tablets contained in an outer cardboard carton

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

PCO Manufacturing
Unit 10
Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/148/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th September 2012

10 DATE OF REVISION OF THE TEXT

January 2014