Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sinemet Plus 25 mg/100 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet of Sinemet Plus 25 mg/100 mg contains carbidopa (equivalent to 25 mg anhydrous carbidopa) and 100 mg levodopa.

Product imported from Portugal
Each tablet of Sinemet Plus 25 mg/100 mg contains carbidopa and 100 mg levodopa.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets

Product imported from the UK, Spain & Italy
Yellow, oval shaped tablet with a breakline and ‘650’ engraved on one side and plain on the other.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Product imported from Portugal
Yellow, round tablet with ‘650’ engraved on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA1286/009/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/009/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Maize starch
Magnesium stearate
Pregelatinised maize starch
Quinoline yellow (E104)

Product imported from Portugal contains;
Hydroxypropylcellulose,
pregelatinised maize starch,
crospovidone,
microcrystalline cellulose,
magnesium stearate,
quinoline yellow aluminum lacquer (E104)

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 25ºC.
- Store in original package in order to protect from light.

6.5 Nature and contents of container

Blister packs of 90 or 100 tablets contained in an outer cardboard carton.

Not all pack sizes may be marketed.

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
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/148/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 April 2006

Date of last renewal: 07 April 2011

10 DATE OF REVISION OF THE TEXT

June 2017