Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sinemet Plus 25mg/100mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet.
Product imported from Spain:
Yellow oval tablets, one side plain and the other scored and marked '650'.

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

4 CLINICAL PARTICULARS

As per PA1286/009/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/009/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be 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 25°C. Store in the original package in order to protect from light.

6.5 Nature and contents of container

PVC/AL blister packs of 100 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

B&S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/037/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 20th October 2006

Date of Last Renewal: 20th October 2011

10 DATE OF REVISION OF THE TEXT

March 2015