Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sinemet Plus 25mg/100mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet of Sinemet Plus 25mg/100mg 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 Italy:
Yellow, oval tablets, scored and marked '650' 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.

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 starch
Quinoline yellow (E104)

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 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

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

LTT Pharma Limited
Unit 18 Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/023/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th July 2010

10 DATE OF REVISION OF THE TEXT

September 2015