

# 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:*

Dappled yellow, oval-shaped tablets scored and marked ‘650’ 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

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

Store in the original package.  
Do not store above 25°C.

## **6.5 Nature and contents of container**

PVC/Al blisters in a cardboard carton containing 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**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA 1151/001/003

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

Date of first authorisation: 21 May 2004

Date of last renewal: 21 May 2009

## **10 DATE OF REVISION OF THE TEXT**

December 2014