

# 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 of anhydrous carbidopa) and 100 mg levodopa.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablets.

*Product imported from Spain:*

Yellow, oval tablets with '650' on one side and plain on the other.

## 4 CLINICAL PARTICULARS

As per PA23198/004/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23198/004/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Quinoline yellow (E104)  
Pregelatinised starch  
Corn 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 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 to protect from light and moisture.

### 6.5 Nature and contents of container

Each pack contains 100 tablets as 10 blisters of 10 tablets each.

**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**

Not applicable.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/235/001

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

Date of first authorisation: 28<sup>th</sup> February 2025

**10 DATE OF REVISION OF THE TEXT**