

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sinemet CR 50 mg/200 mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains 50 mg carbidopa and 200 mg levodopa.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet.

Product imported from Portugal

Peach-coloured, oval-shaped tablet, deep score on one side, 521 on the other.

The score line is not intended for breaking the tablet.

4 CLINICAL PARTICULARS

As per PA23198/004/005

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/004/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropylcellulose

Magnesium stearate

Poly (vinyl acetate-crotonic acid) copolymer

Quinoline yellow aluminium lake (E 104)

Red iron oxide (E 172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 30 °C.

Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Blisters containing 60 prolonged-release tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/468/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st January 2022

10 DATE OF REVISION OF THE TEXT

January 2024