

8 February 2023



RE: Shortage of Sinemet 100mg/25mg Tabs and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

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Australia

Dear Healthcare Professional,

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This notification is sent by LINK to inform your organisation that due to the shortage of Australian registered **SINEMET 100/25 levodopa/carbidopa 100 mg/25 mg tablet bottle (AUST R: 319330)**, LINK has arranged the supply of an alternative product, **Carbidopa and levodopa tablets, USP 25mg/100mg (ScieGen)** registered and marketed in *USA*

Carbidopa and levodopa tablets, USP 25mg/100mg (ScieGen) is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989* until **28 May 2023**

Carbidopa and levodopa tablets, USP 25mg/100mg (ScieGen) is indicated for:

The treatment of Parkinson's disease and syndrome. It is useful in relieving many of the symptoms of parkinsonism, particularly rigidity and bradykinesia. Carbidopa and levodopa tablets frequently are helpful in the management of tremor, dysphagia, sialorrhoea and postural instability associated with Parkinson's disease and syndrome.

The s19A approved *USA* product is identical in active ingredient and strength to the Australian registered product. The product is labelled in English. Please refer to the table below for differences between the products.

	ARTG product: SINEMET 100/25 levodopa/carbidopa 100 mg/25 mg tablet bottle AUST R: 319330	S19A product: Carbidopa and levodopa tablets, USP 25mg/100mg (ScieGen)
Presentation	Yellow oval tablet with 650 and a score line on one side and plain on the other. Supplied in bottles of 100	Light yellow, mottled, round, uncoated tablets debossed with 'SG' on one side and '458' on the other. Bottle of 100s
Excipients	microcrystalline cellulose magnesium stearate pregelatinised maize starch maize starch quinoline yellow (aka D&C Yellow #10)	microcrystalline cellulose magnesium stearate pregelatinized starch hydroxypropyl cellulose D&C Yellow #10 (aka quinoline yellow) crospovidone
Storage	Store below 30°C. Keep in tightly closed container, protected from light and moisture.	Store at 20° to 25°C excursions permitted to 15° to 30°C. Store in a tightly closed container, protected from light and moisture.

Please refer to the Australian Product Information for **SINEMET 100/25 levodopa/carbidopa 100 mg/25 mg tablet bottle (AUST R: 319330)** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **Carbidopa and levodopa tablets, USP 25mg/100mg (ScieGen)**.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with Carbidopa and Levodopa 25mg/100mg Tabs USP (ScieGen) should be reported by healthcare professionals and patients to Link Healthcare Pharmacovigilance. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Link Healthcare Pharmacovigilance can be contacted by phone on 1800 181 060 or via email at pv@linkhealthcare.co.

Link Healthcare Customer Service contact details

Link Healthcare Customer Service can be contacted via phone on 1800 181 060 or via email at customerservice@linkhealthcare.com.au.

Please contact Link Healthcare Customer Service for further information.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of the Australian registered **SINEMET 100/25 levodopa/carbidopa 100 mg/25 mg tablet bottle (AUST R: 319330)**.

Yours sincerely,

Anita Sharma

Anita Sharma B.Pharm
Medicine Access Associate