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MSD

11 February 2021

Dear Healthcare Professional,

Updated information on the supply of

SINEMET CR® (levodopa/carbidopa) 200 mg/50 mg controlled release tablets

Merck Sharp & Dohme (Australia) Pty Ltd (MSD), on behalf of Organon Pharma Pty Limited, wishes to update you on the supply of **SINEMET CR® 200/50** (carbidopa-levodopa).

Currently, an alternative UK version of SINEMET CR® has been supplied on a temporary basis under Section 19A of the *Therapeutic Goods Act 1989*, due to a supply shortage of a previously supplied SINEMET CR®. The shortage situation has been resolved and a registered Australian SINEMET CR® product is now available.

The newly registered SINEMET CR® product will be exactly the same in formulation and appearance as the version currently supplied under Section 19A. However the quantity will change from 60 tablets supplied in a blister pack to a quantity of 100 tablets supplied in a bottle.

	Previously supplied product (prior to shortage)	Alternative UK product currently supplied under section 19A (during shortage)	Newly registered Australian Product (post shortage)
Tablet Appearance	Dappled, purple, oval tablet, plain on one side and marked with 521 	Peach-coloured, oval shaped, biconvex tablets, deep-scored on one side and the other marked '521' 	Peach-coloured, oval shaped, biconvex tablets, deep-scored on one side and the other marked '521' 
Quantity	100 tablets	60 tablets	100 tablets
Container type	Bottle	Blister pack	Bottle
Excipients	Hyprolose, magnesium stearate, hypromellose, indigo carmine and allura red AC	Hyprolose, magnesium stearate, crotonic acid-polyvinylacetate copolymer, iron oxide red, quinoline yellow aluminium lake	Hyprolose, magnesium stearate, crotonic acid-polyvinylacetate copolymer, iron oxide red, quinoline yellow aluminium lake

Note that the tablets have a non-functional score line. The tablets must NOT be broken and should be taken as a whole.

Swallow tablets whole, with a glass of water. In order to maintain the slow-release properties, do not chew or crush the tablets. In addition, each patient may have to be re-titrated individually, under the supervision of a doctor, to ensure the appropriate daily dose is administered for the appropriate clinical response.

Please refer to the SINEMET CR® 200/50 Australian Product Information for further information about the product, which is available via https://www.ebs.tga.gov.au/.

SINEMET CR 50 mg/ 200mg tablets will be available for pharmacists to order via normal wholesaler channels.

Please forward this information to relevant staff members in your organisation.

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 SINEMET CR 50 mg/ 200mg Tablets, should be reported to MSD on 1800 023 135. Alternatively, this information can be reported to the TGA at www.tga.gov.au/reporting-problems.

Yours sincerely,

Dr Gary Jankelowitz
Medical Director
MSD Australia

Julie Mullan
Medical Director
Organon