

March 2020

**MSD**

Merck Sharp & Dohme (Australia) Pty Limited  
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Dear Healthcare Professional,

**Shortage and alternative supply arrangement under  
Section 19A of the *Therapeutic Goods Act 1989* for:  
SINEMET CR® (levodopa/carbidopa) 200 mg/50 mg modified release tablets  
AUST R 171694**



Merck Sharp & Dohme (Australia) Pty Ltd (MSD) has been able to arrange supply of an alternative product to the Australian registered medicine SINEMET CR®, on a temporary basis under Section 19A of the *Therapeutic Goods Act 1989*. SINEMET CR® is in short supply due to a manufacturing constraint with a third-party contractor and this affects Australia as well as other countries.

This alternative product is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until 31 August 2020 for the following indication(s):

*Idiopathic parkinsonism, where standard formulations containing levodopa/carbidopa have produced inadequate control. Experience is limited in patients who have not been treated with levodopa before.*

The alternative product is registered and marketed in the United Kingdom (UK) under the brand name "SINEMET CR 50 mg/ 200mg Prolonged-Release Tablets".

Please note the following information regarding differences between the two products:

|                          | <b>Alternative UK product under section 19A</b>   | <b>Currently Registered Australian Product</b>  |
|--------------------------|---|---|
| <b>Tablet Appearance</b> | Peach-coloured, oval shaped, biconvex tablets, one side deep-scored and the other marked '521'<br> | Dappled, purple, oval tablet, plain on one side with 521 on the other<br> |
| <b>Quantity</b>          | 60 tablets  | 100 tablets   |
| <b>Container type</b>    | Blister pack  | Bottle  |
| <b>Package Insert</b>    | UK patient leaflet included   | No leaflet included   |

|                          | <b>Alternative UK product under section 19A</b>  | <b>Currently Registered Australian Product</b>                                |
|--------------------------|--|---|
| <b>Contraindications</b> | Additional Contraindications:<br><ul style="list-style-type: none"> <li>- Sinemet CR or Half Sinemet CR* should not be given when administration of a sympathomimetic amine is contraindicated.</li> <li>- Use in patients with severe psychoses.</li> </ul> |   |
| <b>Excipients</b>        | Hydroxypropylcellulose, Magnesium Stearate, Poly (Vinyl Acetate-Crotonic Acid) Copolymer, Quinoline Yellow 10 Aluminium Lake E104, Red Iron Oxide E172   | Hyprolose, magnesium stearate, hypromellose, Indigo Carmine and Allura Red AC |

\* Note that the UK 'Half Sinemet CR' product will not be available under section 19A of the *Therapeutic Goods Act 1989*.

**Note that although the new tablets have a non-functional score line, they should not be halved.** Swallow tablets whole, with a glass of water. In order to maintain the slow-release properties, do not chew or crush the tablets.

Please refer to the Australian Product Information for recommended dosing and adverse reaction profile available via <https://www.ebs.tga.gov.au/>.

#### **PBS Reimbursement**

This item is listed on the PBS and is substitutable by pharmacists according to 'a' flagging brand equivalence requirements. The product is supplied in packs of 60 tablets (maximum quantity to be reimbursed is 1.7 packs, equivalent to 100 tablets).

#### **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 Prolonged-Release Tablets, should be reported to MSD on 1800 818 553. Alternatively, this information can be reported to the TGA.

#### **Supply**

SINEMET CR 50 mg/ 200mg Prolonged-Release Tablets will be available for pharmacists to order via normal wholesaler channels.

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

Yours sincerely,



Dr Gary Jankelowitz  
 Medical Director  
**MSD Australia**