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CAUTION IN USE COMMUNICATION - IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS

Changes to guidance on tablet subdivision and tablet removal from blister packaging

Sinemet® Plus (carbidopa/levodopa) 25mg/100mg Tablets- PA1286/9/4
Sinemet® (carbidopa/levodopa) 12.5mg/50mg Tablets - PA1286/9/2

Dear Healthcare Professional,

Merck Sharp & Dohme Ireland (Human Health) Limited ('MSD'), in agreement with the Health Products Regulatory Authority (HPRA), would like to inform you of the following:

MSD has received a number of complaints from patients in Ireland of Sinemet® Plus (carbidopa/levodopa) 25mg/100mg tablets breaking when they were removed from their blister packaging. (Note that Sinemet® 12.5mg/50mg tablets are of a similar tablet design, package configuration, and formulation as the 25mg/100mg tablets, so this letter applies to both products.)

In order to ensure that patients take the correct dose of Sinemet® Plus 25mg/100mg tablets and Sinemet® 12.5mg/50mg, please advise your patients as follows:

- The score line on the tablets is <u>not intended</u> to subdivide the tablet into two equal doses and it should not be used in that way.
- If the tablet must be subdivided to aid in swallowing, the tablet should be consumed only if the whole dose (all parts of the tablet) can be taken.
- Do not apply too much force when removing the tablet from the blister.
- If the tablet breaks when it is removed from the blister, the tablet should be consumed only if the whole dose can be taken. If it cannot, the pieces of the broken tablet should be discarded and another tablet taken from the blister.
- Administration of a partial dose may result in worsening of symptoms.

Additionally:

1. For Sinemet® Plus 25mg/100mg tablets, MSD will update the Summary of Product Characteristics (SmPC) and Package Leaflet (PL) to advise HCPs and patients that these tablets should not be subdivided to obtain two equal doses. The SmPC and PL will be updated to advise HCPs and patients that '***The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses'***.

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2. For Sinemet® 12.5mg/50mg tablets, MSD will update the SmPC and PL to advise HCPs and patients that these tablets, if subdivided to aid in swallowing, can be consumed only if the whole dose can be taken. The wording in the current approved SmPC for Sinemet® 12.5mg/50mg tablets states '***The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses'***. For this reason, no SmPC update is proposed regarding subdivision for fractional dosing. However, the current approved PL for Sinemet® 12.5mg/50mg tablets will be updated to include this wording.

Instructions regarding the administration of other presentations of Sinemet® remain unchanged.

We would appreciate if you could please **immediately** ensure that all of your relevant staff are made aware of the details outlined in this letter and that the information is then communicated to your patients.

Call for reporting

Please note that suspected adverse reactions should be reported to the HPRA electronically via the website at www.hpra.ie or email: medsafety@hpra.ie.

The authorised product information for these medicines is available at www.hpra.ie and at www.medicines.ie.

Company contact point

If you have any questions, please contact us at:
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Medical Information e-mail: medinfo_ireland@merck.com

Yours sincerely,

Ceara Belviso

Dr. Ceara Belviso
Director of Medical Affairs