**MSD Ireland (Human Health)**
Red Oak North,
South County Business Park,
Leopardstown, Dublin,
D18 X5K7 Ireland
T +353 (0)1 299 8700
F +353 (0)1 299 8701
E info@msd.ie
msd.ie

**14th December 2020**

**CAUTION IN USE COMMUNICATION**
**IMPORTANT REMINDER**
**INFORMATION FOR HEALTHCARE PROFESSIONALS**

**THIS IS A REMINDER LETTER OF INFORMATION CONVEYED ON 2ND JUNE 2020 REGARDING CHANGES TO GUIDANCE ON SINEMET® TABLET SUBDIVISION AND TABLET REMOVAL FROM THE BLISTER PACKAGING.**

**COMMUNICATION OF THE INFORMATION BELOW TO PATIENTS WOULD BE GREATLY APPRECIATED.**

**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 **not intended** 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.
- MSD is continuing to work on actions to reduce the incidence of tablet breakage, and the above points are important as an interim measure.

**MSD Ireland (Human Health)**
Red Oak North,
South County Business Park,
Leopardstown, Dublin,
D18 X5K7 Ireland
T +353 (0)1 299 8700
F +353 (0)1 299 8701
E info@msd.ie
msd.ie

Additionally:

1. For Sinemet® Plus 25mg/100mg tablets, MSD updated the Summary of Product Characteristics (SmPC) and Package Leaflet (PL) to reflect the new guidance stated above on September 10th 2020.
2. For Sinemet® 12.5mg/50mg tablets, MSD updated the SmPC and PL to reflect the new guidance stated above on 10th September 2020.
3. Instructions regarding the administration of other presentations of Sinemet® remain unchanged.
4. Please consult the SmPC prior to prescribing Sinemet. The most up to date SmPCs are available at www.medicines.ie.

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:
MSD, Red Oak North
South County Business Park,
Leopardstown,
Dublin 18,
Telephone: +353 1 299 8700
Medical Information e-mail: medinfo_ireland@merck.com

Yours sincerely,

Ceara Belviso

Dr. Ceara Belviso
Director of Medical Affairs