Organon Pharma (Ireland) Limited
2 Dublin Landings
N Wall Quay - North Dock
Dublin
D01 V4A3

August 2021

IMPORTANT INFORMATION
FOR HEALTHCARE PROFESSIONALS

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

Packaging Change - from Blister packs to HDPE Bottles

Dear Healthcare Professional,

Organon Pharma (Ireland) Limited[1] and 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 packaging change for the above products:

Sinemet® Plus (carbidopa/levodopa) 25mg/100mg tablets will shortly become available in HDPE[2] bottles. This switch to bottles will replace the blister packaging over the coming months. It is anticipated that both blister and bottle packaging will be available during this transitional period.

This change in packaging is in response to a number of reports from patients in Ireland who experienced tablet breakages with Sinemet® Plus (carbidopa/levodopa) 25mg/100mg tablets during removal of the tablets from their blister packaging. Supplying the tablets in HDPE bottles instead of in blister packs is intended to address that issue.

Previous communications sent to you in relation to use of the tablet score-line remain unchanged. (Please see summary below.)

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

- The score-line on the tablets is <u>not intended</u> to sub-divide the tablet into two equal doses, and it should not be used in that way.
- If a tablet must be sub-divided to aid in swallowing, the tablet should be consumed only if the whole dose (i.e. all parts of the tablet) can be taken.
- Administration of a partial dose may result in worsening of symptoms.

Additionally:

Sinemet® 12.5mg/50mg tablets are of a similar tablet design, package configuration and formulation as the 25mg/100mg tablets. Please also note that as part of this packaging change, we intend to also transition Sinemet 12.5mg/50mg from blister packs to HDPE bottles in due course.

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

[1] Note; Organon & Co., Inc. has spun off as a separate company from Merck & Co., Inc. of Kenilworth, NJ, USA on 2 June 2021, and in Ireland this means that Organon Pharma (Ireland) Limited will continue to market the product in the market. MSD is in the process of transferring its marketing authorisation for Sinemet to Organon.
[2] HDPE - High Density PolyEthylene

IE-SID-110000, Date of Preparation August 2021

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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: +353 1582 8250 (Organon Pharma (Ireland) Ltd)

Yours sincerely,

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Karin Hagen
Medical Director UK&ENI
Organon Pharma (Ireland) Limited