

MSD

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Dear Health Care Professional,

Merck Sharp & Dohme (New Zealand) Limited wishes to inform you of upcoming changes to the shape, colour, markings and inactive ingredients of SINEMET[®] (carbidopa-levodopa) 25/100 mg and 25/250 mg tablets.

CHANGE TO TABLET APPEARANCE and INACTIVE INGREDIENTS

The new tablet presentations will have a score line. The score lines on the new SINEMET[®] 25/100 mg and SINEMET[®] 25/250 mg tablets are functional, so they can be used to divide each tablet into two equal half doses.

The table below contains a comparison of the current and new tablet appearances and inactive ingredients. Please note, tablets are not shown at actual size.

Tablet	Current tablet appearance	New tablet appearance
SINEMET [®] 25mg/250mg Tablets	 Light-blue dappled, round tablet, with "654" on one side and plain on the other	 Light-blue dappled, oval tablet, one side plain and the other side scored and marked "654"
	Current inactive ingredients	New inactive ingredients
	Each tablet contains the following inactive ingredients: Hydroxypropyl cellulose, crospovidone, microcrystalline cellulose, magnesium stearate, pregelatinised starch, indigo carmine AL.	Each tablet contains the following inactive ingredients: Pregelatinised starch, corn starch, microcrystalline cellulose, magnesium stearate, indigotine.
SINEMET [®] 25mg/100mg Tablets	 Yellow, round tablet with "650" on one side and plain on the other side	 Yellow, oval tablet, one side plain and the other side scored and marked "650"
	Current inactive ingredients	New inactive ingredients
	Each tablet contains the following inactive ingredients: Hydroxypropyl cellulose, crospovidone, microcrystalline cellulose, magnesium stearate, pregelatinised starch, quinoline yellow.	Each tablet contains the following inactive ingredients: Pregelatinised starch, corn starch, microcrystalline cellulose, magnesium stearate, quinoline yellow.

Important Dosing Changes

The new presentation is **scored**. Patients taking the current SINEMET tablets may require reassessment of their dosage regimen.

The Data Sheet has been revised to reflect how the changes affect dosing and administration. In particular, references to half-tablet dosing have been included. For further information, please refer to the SINEMET Data Sheet available at www.medsafe.govt.nz. Selected excerpts from the *Dose and method of administration* subsections of the Data Sheet provided below:

4.2 Dose and method of administration

Dose

The optimum daily dosage of SINEMET must be determined by careful titration in each patient. SINEMET tablets are available in a 1:4 ratio of carbidopa to levodopa (SINEMET 25/100) as well as a 1:10 ratio (SINEMET 25/250). Tablets of the two ratios may be given separately or combined as needed to provide the optimum dosage. Each tablet of SINEMET is designed to divide in half with minimal pressure.

The total levodopa dose in a 24-hr period should be similar and divided accordingly, with doses given approximately every three to four hours.

Usual Initial Dose

Dosage is best initiated with one tablet of SINEMET 25/100 three times a day. This dosage schedule provided 75 mg of carbidopa per day. Dosage may be increased by one tablet every day or every other day (given at intervals of 3-4 hours), as necessary, until a dosage equivalent of eight tablets of SINEMET 25/100 a day is reached.

Dosage is best initiated with SINEMET 25/100 in patients who have not been treated with SINEMET before. For patients starting with SINEMET 25/250, the initial dose is one half tablet taken once or twice daily. However, this may not provide the optimal amount of carbidopa needed by many patients. If necessary, add 1/2 tablet every day or every other day until optimal response is reached.

Response has been observed in one day, and sometimes after one dose. Fully effective doses usually are reached within seven days as compared to weeks or months with levodopa alone.

Maintenance

Therapy should be individualised and adjusted according to the desired therapeutic response. At least 70 to 100 mg of carbidopa per day should be provided for optimal inhibition of extracerebral decarboxylation of levodopa. When a greater proportion of carbidopa is required, one tablet of SINEMET 25/100 may be substituted.

When more levodopa is required, SINEMET 25/250 should be substituted for SINEMET 25/100. If necessary, the dosage of SINEMET 25/250 may be increased by one half or one tablet every day or every other day, up to a maximum of eight tablets a day. Experience with total daily dosages of carbidopa greater than 200 mg is limited.

Please ensure that all of your relevant staff are made aware of the contents of this letter and that the information is communicated to your patients.

Should you have any questions regarding the new presentation or formulation, please contact our MSD Medical Information on 0800 500 673. For stock enquiries, please contact our Customer Services Department on 0800 800 673.

Kind regards,

Dr Stefan Orange
Medical Director
Merck Sharp & Dohme (New Zealand) Limited