

**IMPORTANT CHANGES TO ^{Pr}SINEMET[®] (levodopa and
carbidopa tablets, USP) and ^{Pr}SINEMET[®] CR (levodopa and
carbidopa tablets controlled release tablets)**



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**Subject: IMPORTANT CHANGES TO ^{Pr}SINEMET[®] (levodopa and carbidopa
tablets, USP) and ^{Pr}SINEMET[®] CR (levodopa and carbidopa tablets controlled release
tablets)**

Merck Canada Inc. would like to advise healthcare professionals and patients of important changes to SINEMET[®] 100/10, SINEMET[®] 250/25, SINEMET[®] CR 100/25 and SINEMET[®] CR 200/50 tablets. These changes are specific to size, color, shape, markings and non-medicinal ingredients.

It is important to note that these new tablets are not scored and must not be cut or broken.





For additional information, please refer to the [product monograph](#) or contact Merck Customer Information Center at 1-800-567-2594

PrSINEMET® 100/10 and PrSINEMET® 250/25 Comparison of Tablet Appearance, Non-Medicinal Ingredients and Storage Conditions

Tablet Strength	Previous Tablet Appearance	New Tablet Appearance
100 mg / 10 mg	 <p>Dark dapple blue, oval, scored, uncoated tablet, with 647 on one side and SINEMET on the other side</p>	 <p>Light dapple-blue, round, uncoated tablets, plain on one side and “647” on the other</p>
	Previous Non-Medicinal Ingredients	New Non-Medicinal Ingredients
	Cornstarch, magnesium stearate, microcrystalline cellulose, pregelatinized starch, FD&C Blue No. 2	crospovidone, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, FD&C Blue No. 2 Aluminum Lake
	Previous Storage and Stability	New Storage and Stability
Store your tablets at 15°C-30°C in a tightly closed container. Protect from sunlight.	Store your tablets at room temperature (15°C-30°C). Store in tightly closed container, protected from light and moisture.	
250 mg / 25 mg	 <p>Light dapple blue, oval, scored, uncoated tablet, with 654 on one side and SINEMET on the other side</p>	 <p>Light dapple-blue, round, uncoated tablets, plain on one side and “654” on the other</p>
	Previous Non-Medicinal Ingredients	New Non-Medicinal Ingredients
	Cornstarch, magnesium stearate, microcrystalline cellulose, pregelatinized starch, FD&C Blue No. 2	crospovidone, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, FD&C Blue No. 2 Aluminum Lake
	Previous Storage and Stability	New Storage and Stability
Store your tablets at 15°C-30°C in a tightly closed container. Protect from sunlight.	Store your tablets at room temperature (15°C-30°C). Store in tightly closed container, protected from light and moisture.	

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PrSINEMET® CR 100/25 and PrSINEMET® CR 200/50 Comparison of Tablet Appearance and Non-Medicinal Ingredients and Storage Conditions

Tablet Strength	Previous Tablet Appearance	New Tablet Appearance
100 mg / 25 mg	 <p>Pink-colored, oval-shaped, biconvex, compressed tablet, engraved 601 with bar on one side and SINEMET CR on the other</p>	 <p>Dappled purple, oval-shaped, compressed tablet, engraved 601 on one side and plain on the other</p>
	Previous Non-Medicinal Ingredients	New Non-Medicinal Ingredients
	Non-medicinal ingredients: hydroxypropyl cellulose, magnesium stearate, polyvinylacetatecrotonic acid copolymer and red ferric acid,	Non-medicinal ingredients: hydroxypropylcellulose, hypromellose, magnesium stearate, FD&C Blue No. 2 Aluminum Lake and FD&C Red No. 40 Aluminum Lake
	Previous Storage and Stability	New Storage and Stability
	Store your tablets at 15°C-30°C in a tightly closed container. Protect from sunlight.	Store at room temperature (15°C-30°C) in a tightly closed container, protected from light and moisture.
200 mg / 50 mg	 <p>Peach-colored, oval-shaped, biconvex, scored compressed tablet, engraved 521 on one side and SINEMET CR on the other</p>	 <p>Dappled purple, oval-shaped, compressed tablet, engraved 521 on one side and plain on the other</p>
	Previous Non-Medicinal Ingredients	New Non-Medicinal Ingredients
	Non-medicinal ingredients: hydroxypropyl cellulose, magnesium stearate, polyvinylacetatecrotonic acid copolymer, red ferric oxide, and D&C Yellow No. 10 Aluminum Lake.	Non-medicinal ingredients: hydroxypropylcellulose, hypromellose, magnesium stearate, FD&C Blue No. 2 Aluminum Lake and FD&C Red No. 40 Aluminum Lake
	Previous Storage and Stability	New Storage and Stability
	Store your tablets at 15°C-30°C in a tightly closed container. Protect from sunlight.	Store at room temperature (15°C-30°C) in a tightly closed container, protected from light and moisture.

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