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## on Drugs and Therapeutics

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### IN THIS ISSUE

**In Brief: New Warnings for Carbidopa/Levodopa Products**..... p 72

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## on Drugs and Therapeutics

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### IN BRIEF

#### New Warnings for Carbidopa/Levodopa Products

The FDA has required that the labels of all carbidopa/levodopa-containing products (*Crexont, Dhivy, Duopa, Rytary, Sinemet, Sinemet CR, Stalevo, Vyalev*) include a warning about the risk of vitamin B6 (pyridoxine) deficiency and vitamin B6 deficiency-related seizures associated with their use. The combination of carbidopa/levodopa is the most effective treatment for the motor symptoms of Parkinson's disease and recent evidence favors its early use.<sup>1</sup>

Vitamin B6 is required for the conversion of levodopa to dopamine; high doses of levodopa can deplete vitamin B6 levels during the conversion process. Carbidopa also binds to the active form of vitamin B6.

The new warnings were based on a review that identified 14 cases of seizures, 2 of which were fatal, associated with vitamin B6 deficiency in patients receiving >1000 mg/day of oral or enteral carbidopa/levodopa. The seizures were generally focal-onset seizures with secondary generalization; some patients had seizures that progressed to status epilepticus. Seizures resolved in the patients who received vitamin B6 supplementation. The majority of cases did not respond to antiseizure drugs, some of which can cause vitamin B6 deficiency. Other signs of vitamin B6 deficiency, including elevated homocysteine levels, microcytic or normocytic anemia, and neuropsychiatric symptoms, were also reported in the case patients.<sup>2</sup>

The updated labels recommend monitoring vitamin B6 levels at baseline, periodically during treatment, and when symptoms of vitamin B6 deficiency develop. Vitamin B6 supplementation is recommended as needed. ■

1. Drugs for Parkinson's disease. *Med Lett Drugs Ther* 2021; 63:25.
2. FDA Drug Safety Communication. FDA is requiring warning about vitamin B6 deficiency and associated seizures for drug products containing carbidopa/levodopa. March 20, 2026. Available at: <https://bit.ly/4trJwC7>. Accessed April 9, 2026.

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