Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate the latest up-to-date drug safety information.

FDA Is Requiring Warning about Vitamin B6 Deficiency and Associated Seizures for Drug Products

U.S. Food & Drug Administration Publication Date:

03/20/2026

Drug Indication:

Treat symptoms of Parkinson's disease.

Safety Topic:

All drug products containing carbidopa/levodopa are being required the addition of a warning to the prescribing information to state that these medications can cause vitamin B6 deficiency and vitamin B6 deficiency-associated seizures.

It is for this reason that we are notifying you that on March 20, 2026, the U.S. Food and Drug Administration (FDA) published a safety communication for all drug products containing carbidopa/levodopa.

Reason for Communication

The FDA has notified application holders for all drug products containing carbidopa/levodopa that the Agency is requiring the addition of a warning, and corresponding revisions, to the prescribing information to state that these medications can cause vitamin B6 deficiency and vitamin B6 deficiency-associated seizures. The warning directs health care professionals to evaluate baseline vitamin B6 levels prior to starting treatment with carbidopa/levodopa therapies and periodically while on treatment and to supplement with vitamin B6 as necessary.

The FDA conducted a safety review and identified 14 cases of seizures linked to vitamin B6 deficiency in patients using drug products containing carbidopa/levodopa. The 14 cases included postmarketing reports submitted to FDA or found in the medical literature, so there are likely additional cases for which the FDA is unaware. All of the reviewed cases involved levodopa doses exceeding 1,000 mg daily, with higher doses (>1,500 mg levodopa) associated with shorter duration from treatment initiation to identification of vitamin B6 deficiency.

Pharmacy Required Action

Advise patients that they should be aware that taking drug products containing carbidopa/levodopa can lead to vitamin B6 deficiency, which can increase the risk of seizures. To monitor for vitamin B6 deficiency, their health care professional should evaluate their vitamin B6 levels before starting treatment with a drug product containing carbidopa/levodopa, periodically during treatment, and if symptoms of vitamin B6 deficiency appear during treatment.

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252-ext.219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

REFERENCES:

1. U.S. Food and Drug Administration. (2026). *FDA Is Requiring Warning about Vitamin B6 Deficiency and Associated Seizures for Drug Products Containing Carbidopa/Levodopa*. https://www.fda.gov/media/191605/download?attachment