

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Rising Pharma Holdings, Inc, is initiating a recall to the Retail Level on Carbidopa, Levodopa, Entacapone Tablets 25 mg / 100 mg / 200 mg (ANDA# 213212) batch # CS25070 manufactured by Suven Pharmaceuticals Limited located in Telangana, India and marketed by Rising Pharma Holdings, Inc., USA.

This recall has been initiated following a product complaint received from a pharmacy, where a pharmacist reported that sealed medication bottle contained Carbidopa, Levodopa, and Entacapone film-coated tablets (37.5 mg/150 mg/200 mg) instead of labelled lower strength Carbidopa, Levodopa, and Entacapone film-coated tablets (25 mg/100 mg/200 mg).

Suven Pharmaceuticals Limited has conducted an investigation into the reported complaint and determined that the issue is attributable to a low-level packaging defect, limited to a small number of units. A health hazard assessment performed by Rising Pharma Holdings, Inc. concluded that the presence of higher-strength Carbidopa, Levodopa, and Entacapone tablets in place of the lower-strength tablets is unlikely to pose a significant risk of adverse health outcomes. Based on the available data, no safety concerns for patients are anticipated.

This batch was distributed between June 11th 2025 to July 28th 2025.

PRODUCT: Carbidopa, Levodopa, Entacapone Tablets 25 mg/100 mg/200 mg

NDC NUMBER: 16571-691-01

LOT NUMBER: CS25070

EXPIRATION DATE: 03/2027

DISTRIBUTION DATES: June 11th 2025 to July 28th 2025