

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.

Dr. Reddy's Laboratories Inc. is issuing a recall for Levetiracetam in 0.75% in Sodium Chloride Injection 1,000 mg/100 mL (10 mg/mL). This recall is being carried out to the consumer level.

The recall has been initiated due to product complaint received for mislabeling. The pre-printed text content on the infusion bag (primary container) for the lot indicates product information as Levetiracetam 0.82% sodium chloride injection (500 mg/100 mL). The label on the aluminum over wrap has the product information as Levetiracetam in 0.75% Sodium Chloride Injection (1,000 mg/100 ml).

Patients who are administered the mislabeled product will likely experience adverse events. Because the infusion bag is labelled as 500 mg/100 mL but actually contains 1,000 mg/100 mL dose, the patient could receive double the dose of intravenous Levetiracetam than intended which could lead to immediate and serious side effects including hypersensitivity reactions, liver injury, hematological toxicity, somnolence, fatigue, dizziness, coordination difficulties, agitation, aggression, depressed level of consciousness, respiratory depression, and coma. Patients receiving high doses of Levetiracetam by rapid intravenous infusion for the treatment of status epilepticus would be most at risk for severe adverse events.

The product Distribution Dates: November 04, 2024 – November 06, 2024.

NDC Number	Product Overwrap Description	Product Infusion Bag Primary Description	Lot Number	Expiration Date
43598-635-52	Levetiracetam in 0.75% Sodium Chloride Injection 1,000 mg/100 mL	Levetiracetam in 0.82% Sodium Chloride Injection 500 mg/100 mL single-dose bag.	A1540076	08/2026
43598-636-52	Levetiracetam in 0.75% Sodium Chloride Injection 1,000 mg/100 mL	Levetiracetam in 0.75% Sodium Chloride Injection 1,000 mg/100 mL single-dose bag	A1540076	08/2026

NDC Number	Carton Description	Lot Number	Expiration Date
43598-636-10	Levetiracetam in 0.75% Sodium Chloride Injection 1,000 mg/100 mL 10 Single-Dose Bags	A1540076	08/2026