Dr. Reddy's – Recall of levetiracetam injection

- On March 13, 2025, Dr. Reddy's announced a consumer level recall of one lot of levetiracetam in 0.75% sodium chloride injection 1,000 mg/100 mL single-dose infusion bags because the infusion bag is incorrectly labeled as levetiracetam in 0.82% sodium chloride injection 500 mg/100 mL single-dose bag, while the aluminum overwrap packaging correctly identifies the product as levetiracetam in 0.75% sodium chloride injection 1,000 mg/100 mL.
    - Clinical Services identified potentially impacted members and will send notifications to the members and their prescribers.
    - The member letter advises members to contact their prescribers or pharmacy for questions.
- Levetiracetam injection was distributed nationwide between November 4, 2024 and November 6, 2024.

Product Description	NDC#	Lot# (Expiration Date)
Levetiracetam in 0.75% Sodium Chloride Injection 1,000 mg/100 mL	43598-635-52 43598-636-52 43598-636-10 (carton of 10 bags)	A1540076 (8/2026)

- Levetiracetam injection is indicated for adjunct therapy in adults (≥ 16 years of age) with the following seizure types when oral administration is temporarily not feasible: partial onset seizures, myoclonic seizures in patients with juvenile myoclonic epilepsy, and primary generalized tonic-clonic seizures.
- 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.
- To date, Dr. Reddy's has not received any reports of adverse events related to this recall.
- Anyone with the affected lots on hand should stop distribution and return product.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
- Contact Dr. Reddy's Medical Information Call Center by phone at **1-888-375-3784** for questions regarding this recall.