COMMUNICATION

COM-2025-016

17 MARCH 2025

URGENT PLEASE REVIEW

Recall 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 recall information.

U.S. Food & Drug Administration Publication Date:

03/13/2025

Drug Information:

National Drug Code

Refer to the table included in the notification

Product Description

Levetiracetam in 0.75% Sodium Chloride Injection 1,000 mg/100 mL (10 mg/mL) single-dose infusion bags

Lot Number

Refer to the table included in the notification

Expiration Date

08/2026

Company:

Dr. Reddy's Laboratories Ltd.

QUESTIONS

Call Dr. Reddy's Medical Information Call Center at 1-888-375-3784 Monday – Friday from 8:00 a.m. to 8:00 p.m. ET.

Levetiracetam in Sodium Chloride Injection

It is for this reason that we are notifying you that on 03.13.2025 the U.S. Food and Drug Administration (FDA) published a drug recall for the following product(s): Levetiracetam in 0.75% Sodium Chloride Injection 1,000 mg/100 mL (10 mg/mL).

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

The product is being recalled 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.

Risk Statement:

Patients who are administered the mislabeled product will likely experience adverse events. The patient could receive double the dose of intravenous levetiracetam than intended which could lead to immediate and serious side effects. 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. Dr. Reddy's has not received any reports of adverse events related to this recall.

Description of mislabeled bags being recalled:

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

Description of cartoon being recalled:

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

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/.

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REFERENCES:
1. U.S. Food and Drug Administration. (2025). Dr. Reddy's Issues a Nationwide Recall of Levetiracetam in 0.75% Sodium Chloride Injection 1,000 mg/100 mL, in the U.S., Due to Mislabeling of Infusion Bag. Retrieved March 13, 2025, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dr-reddys-issues-nationwide-recall-levetiracetam-075-sodium-chloride-injection-1000-mg100-ml-us-due
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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