



Dr. Reddy's Laboratories, Inc.
107 College Road East,
Princeton, NJ 08540

URGENT UPDATE: DRUG RECALL
(Consumer Level)

03/13/2025

Levetiracetam in 0.75% in Sodium Chloride Injection
1,000 mg/100 mL (10 mg/mL)

MANUFACTURED BY:
Gland Pharma Limited
Hydrabad, Telangana
India 500043

RECALLED BY:
Dr. Reddy's Laboratories Inc.
600 College Road East, Suite 4000
Princeton, NJ- 08540 USA

Dear Valued Customer:

This is to inform you of a product recall involving:

Levetiracetam in 0.75% in Sodium Chloride Injection
1,000 mg/100 mL (10 mg/mL)

Please refer to the table below & Product Photo:

DESCRIPTION OF MISLABELLED 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 CARTON 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

This recall is being carried out to the CONSUMER level. Please see the product Photo below.

Risk Assessment:

The voluntary 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 in 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).

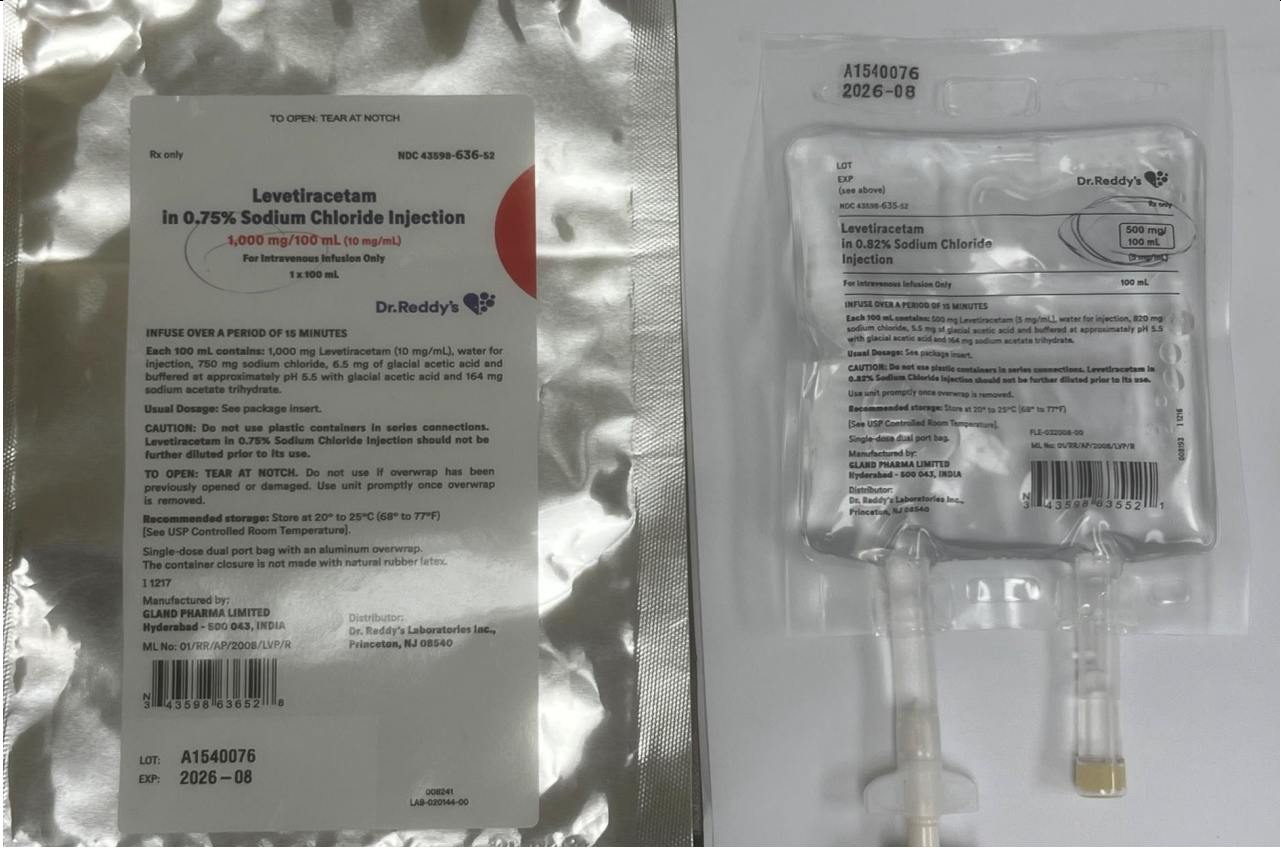
Patients who are administered the mislabeled product will likely experience adverse events. Because the infusion bag is labelled as 500 mg/100 mL but actually contains 1,000 mg/100 mL dose, the patient could receive double the dose of intravenous levetiracetam than intended which could lead to immediate 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



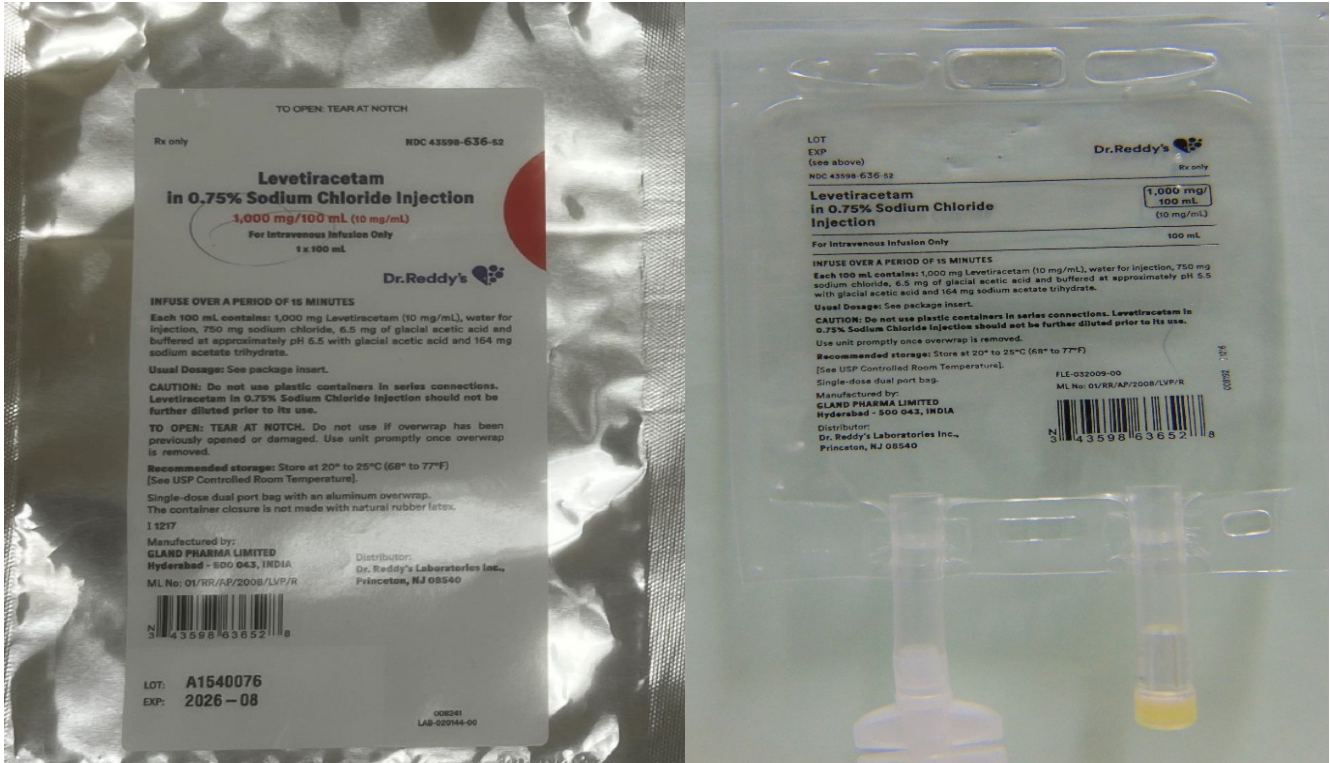
Product Photos

Product Overwrap Description	Product Infusion Bag Primary Description with Error
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.

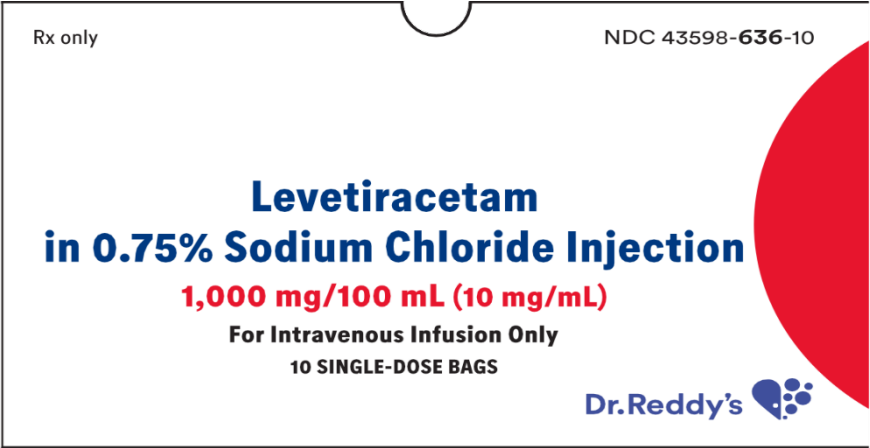




Product Overwrap Description	Product Infusion Bag Primary Description with No Error
Levetiracetam in 0.75% Sodium Chloride Injection 1,000 mg/100 mL	Levetiracetam in 0.75% Sodium Chloride Injection 1,000 mg/100 mL single-dose bag.



Carton Description





Recall Instructions:

Please perform the following activities:

- Examine your inventory immediately for the lot listed above and immediately discontinue distribution and sales of the product lot being recalled. Please quarantine the affected lot of this product.
- If you, as a wholesaler or retailer, have further distributed this product, please identify your retail customers and patients and notify them at once of this product recall.
- Promptly complete the attached recall stock response form even if you have **no** product to return.

Completed Recall Stock Response form can be submitted by any of the below methods:

Phone: 877-645-1584

Fax: 817-868-5362

E-mail: RXrecalls@inmar.com

For questions regarding return of the recalled product please call Inmar at 877-645-1584 Office hours 9am to 5pm (EST) Monday through Friday.

Upon receipt of your Recall Response Form a "Return Kit" will be sent to you. This kit will include:

- Pre-paid shipping label(s)
- Processing labels
- Shipping instructions

This recall is being made with the knowledge of the Food & Drug Administration.

Your cooperation and prompt response to this notice are much appreciated. If you have customer service-related questions, please contact Dr. Reddy's Laboratories at 866-733-3952 during office hours from 9 am to 5 pm (EST) Monday through Friday. For medical-related questions, please contact Dr. Reddy's Laboratories at 888-375-3784 during office hours from 9 am to 5 pm (EST) Monday through Friday.

Signed by:

John Frias



Signer Name: John Frias

Signing Reason: I approve this document

Signing Time: 13-Mar-25 | 5:33:33 AM IST

0D76C5E808AF45D1AD0EBF97FBDA4B7

Sincerely,
John Frias

Director, QA

Dr. Reddy's Laboratories, Inc.

Enclosure(s)

1. Product Labels
2. Recall Return Response Form



UPDATE RECALL STOCK RESPONSE FORM

RECALL of Levetiracetam in 0.75% in Sodium Chloride Injection 1000 mg/100mL (10 mg/mL) (Consumer Level)

03/13/2025

Instructions to Consumers for returning recalled Product:

- 1) Complete below form and return to Inmar for processing.
- 2) For reimbursement, please send a copy of your "Proof of Purchase" such as a pharmacy receipt or a claim from your medical/prescription benefit provider along with the completed response form to Inmar.
- 3) Return completed form and proof of purchase via **FAX: 1-817-868-5362** -or- **E-MAIL: rxrecalls@inmar.com** -or- regular **MAIL: Inmar Pharmaceutical Services, Attn: Recall Coordinator** - One West Fourth Street, Suite 500, Winston Salem, NC 27101

Customer/Patient Name: _____

Address: _____

City: _____

State: _____

Zip: _____

Contact Name (Please Print): _____

Telephone#: _____

Email: _____

Contact Signature: _____

Date: _____

Dr. Reddy's is accepting the below NDC/Lots for Drug Name.

Please fill out the table below indicating how much product you will be returning.

Please attach a picture or scan of the receipt(s) for **ALL** product(s) you will be returning.

IMPORTANT- Send all receipts with this form. A return kit will be sent to you to send back your product. **DO NOT SEND RECEIPTS WITH YOUR RETURN KIT.** They will not be processed and your refund will not be sent.

NDC Number	Product Overwrap Description	Product Infusion Bag Primary Description	Lot Number	Expiration Date	Quantity Returned
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**UPDATE RECALL STOCK RESPONSE FORM****RECALL of Levetiracetam in 0.75% in Sodium Chloride Injection
1000 mg/100mL (10 mg/mL)
(Consumer Level)****03/13/2025**

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

Any adverse events associated with recalled product? ☐ Yes ☐ No

If yes, please explain: _____

Purchased from: Retailer/Wholesaler Name _____

City _____ State _____

If you have any questions regarding this form or product return, please contact Inmar at 877-645-1584 office hours 9am to 5pm (EST) Monday through Friday.

Please fax this form to: 1-817-868-5362 or E-mail: RXrecalls@inmar.com



UPDATE RECALL STOCK RESPONSE FORM

RECALL of Levetiracetam in 0.75% in Sodium Chloride Injection 1,000 mg/100mL (10 mg/mL) (Retail Level)

03/13/2025

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action. **If this form is not filled out correctly and in its entirety, you may not be eligible for credit.**

Company Name _____ DEA # _____

Debit Memo # _____ Original Invoice # _____

**DEA # and Debit Memo # is required, without it, processing of your form will be delayed.*

Address _____

City _____ State _____ Zip _____

Contact Name (please print) _____ Telephone # _____

Contact Signature _____ Date _____

I have checked my stock and:

_____ Do not have any stock of the recalled **items**.

OR

I have quarantined and listed in the box below the quantity of recalled units and will be returning to Inmar. Upon receipt of this Response Form, Inmar, will issue return authorization label(s) and will need _____ # of box labels.

NDC Number	Product Overwrap Description	Product Infusion Bag Primary Description	Lot Number	Expiration Date	Quantity Returned
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UPDATE RECALL STOCK RESPONSE FORM

RECALL of Levetiracetam in 0.75% in Sodium Chloride Injection 1,000 mg/100mL (10 mg/mL) (Retail Level)

03/13/2025

NDC Number	Carton Description	Lot Number	Expiration Date	Quantity Returned
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Wholesalers and Distributors only

☐ I have identified my customers that were shipped or may have been shipped this product. Attached is a list of customers with their contact details who received/may have received this product.

Any adverse events associated with recalled product? ☐ Yes ☐ No

If yes, please explain: _____

If you did not purchase the product directly from the Manufacturer, please complete the below section.

Purchased from: Retailer /Wholesaler Name _____ DEA # _____

City _____ State _____

If you have any questions regarding this form or product return, please contact Inmar at 877-645-1584 office hours 9am to 5pm (EST) Monday through Friday.

Please fax this form to: 1-817-868-5362 or E-mail: RXrecalls@inmar.com