



Dr. Reddy's Laboratories Ltd.
8-2-337, Road No. 3, Banjara Hills
Hyderabad – 500 034, Telangana, India
CIN: L85195TG1984PLC004507
Tel: + 91 40 4900 2900
Fax: + 91 40 4900 2999
Email: mail@drreddys.com
Web: www.drreddys.com

March 13, 2025

National Stock Exchange of India Ltd. (Scrip Code: DRREDDY)
BSE Limited (Scrip Code: 500124)
New York Stock Exchange Inc. (Stock Code: RDY)
NSE IFSC Ltd. (Stock Code: DRREDDY)

Dear Sir/Madam,

Ref: Disclosure under Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015

Please find enclosed a Press Release *viz.* “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”.

This is for your information and records.

Thanking you,

Yours faithfully,
For **Dr. Reddy's Laboratories Limited**

K Randhir Singh
Company Secretary, Compliance Officer & Head-CSR

DR. REDDY'S LABORATORIES LTD.

8-2-337, Road No. 3, Banjara Hills,
Hyderabad - 500034. Telangana, India.

CONTACT	
INVESTOR RELATIONS	MEDIA RELATIONS
RICHA PERIWAL RICHAPERIWAL@DRREDDYS.COM	USHA IYER USHAIYER@DRREDDYS.COM

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

FOR IMMEDIATE RELEASE Hyderabad India; March 13, 2025 –Dr. Reddy’s Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY; along with its subsidiaries together referred to as “Dr. Reddy’s”), is recalling one Batch/Lot No: A1540076 of Levetiracetam in 0.75% Sodium Chloride Injection, 1,000 mg/100 mL (10 mg/mL) single-dose infusion bags to the consumer level, in the United States.

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. 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. Dr. Reddy’s has not received any reports of adverse events related to this recall.

Levetiracetam in 0.75% Sodium Chloride Injection, 1,000 mg/100 mL (10 mg/mL) and Levetiracetam in 0.82% Sodium Chloride Injection, 500 mg/100 mL (5mg/mL) are both 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
- Primary generalized tonic-clonic seizures

Each product is packaged in single-dose infusion bags with an aluminum overwrap, 10 single-dose bags packed in a carton. Identification information such as lot number, expiration date and NDC is presented in the table below. The batch was distributed nationwide between November 4, 2024, and November 6, 2024, to wholesalers.

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

Dr. Reddy's Laboratories, Inc is notifying its distributors and customers to arrange for return of any recalled product. Wholesalers, distributors, hospitals, and pharmacies with an existing inventory of the lot being recalled, should stop use and distribution and quarantine the product immediately for return/replacement of all recalled products. Wholesalers, distributors, and pharmacies that have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product from them. For instructions on returning product or additional assistance, call Inmar at 1-877-645-1584 between the hours of 9 a.m. to 5 p.m. ET, Monday through Friday.

Consumers with questions regarding this recall can contact Dr. Reddy's Medical Information Call Center at 1-888-375-3784 (1-888-DRL-DRUG) between the hours of 8 a.m. to 8 p.m. ET, Monday through Friday. Consumers should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

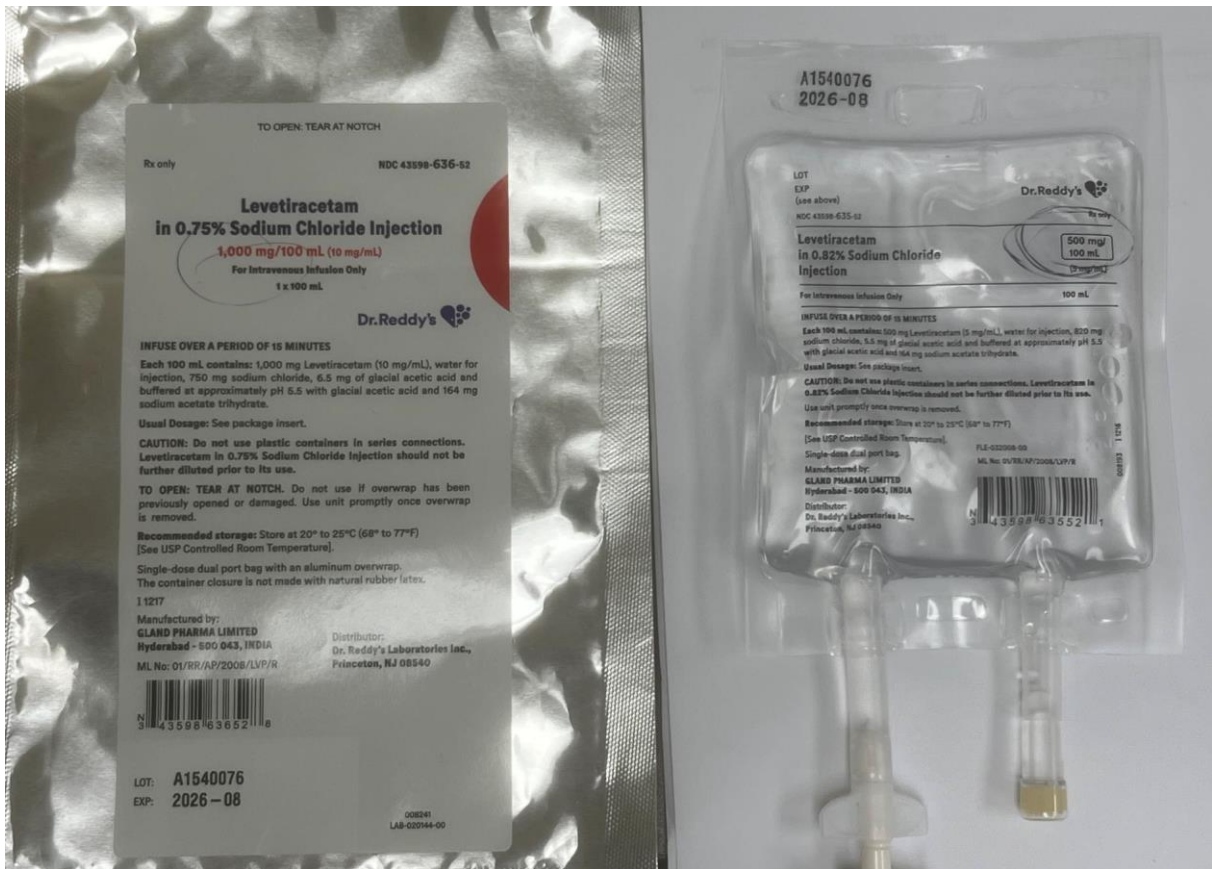
Adverse reactions or quality concerns experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report online at www.fda.gov/medwatch/report.htm.
- Regular Mail or Fax: Download form at www.fda.gov/MedWatch/getforms.htm 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.

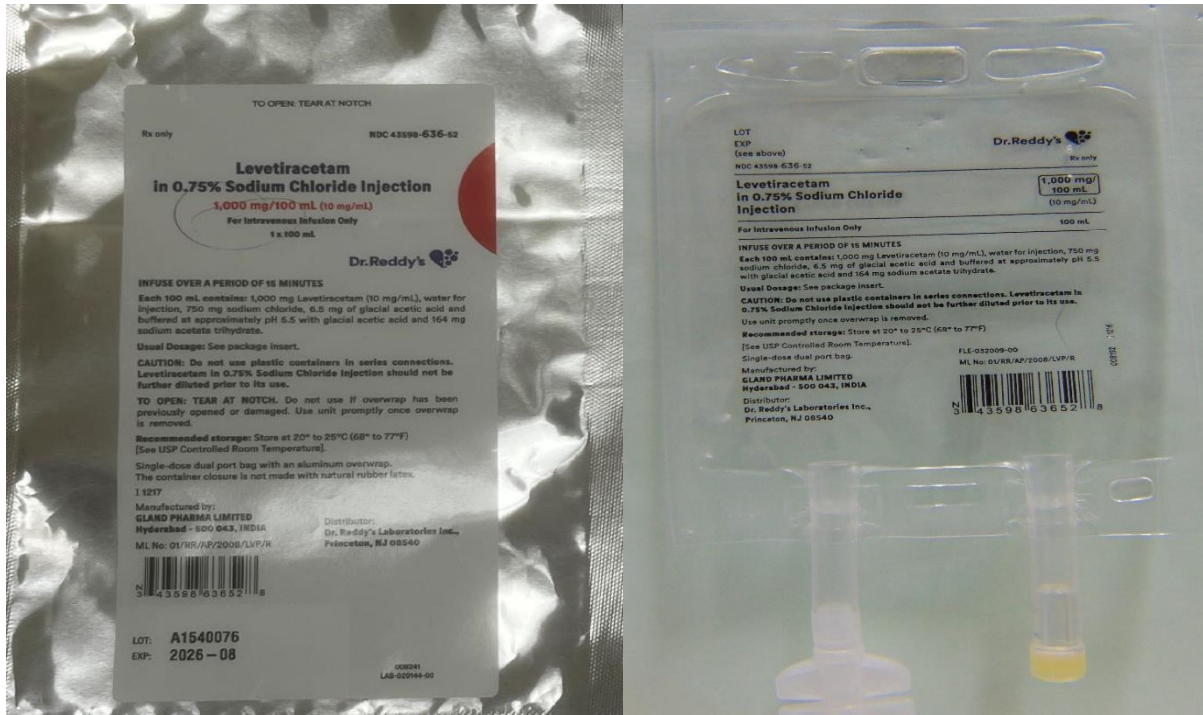
This recall is being executed with the knowledge of the U.S. Food and Drug Administration.

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



RDY-0325-782

About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, we are committed to providing access to affordable and innovative medicines. Driven by our purpose of 'Good Health Can't Wait', we offer a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Our major markets include – USA, India, Russia & CIS countries, China, Brazil and Europe. As a company with a history of deep science that has led to several industry firsts, we continue to plan ahead and invest in businesses of the future. As an early adopter of sustainability and ESG actions, we released our first Sustainability Report in 2004. Our current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance. For more information, log on to: www.drreddys.com.

Disclaimer: This press release may include statements of future expectations and other forward-looking statements that are based on the management's current views and assumptions and involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. In addition to statements which are forward-looking by reason of context, the words "may", "will", "should", "expects", "plans", "intends", "anticipates", "believes", "estimates", "predicts", "potential", or "continue" and similar expressions identify forward-looking statements. Actual results, performance or events may differ materially from those in such statements due to without limitation, (i) general economic conditions such as performance of financial markets,

credit defaults , currency exchange rates, interest rates, persistency levels and frequency / severity of insured loss events, (ii) mortality and morbidity levels and trends, (iii) changing levels of competition and general competitive factors, (iv) changes in laws and regulations and in the policies of central banks and/or governments, (v) the impact of acquisitions or reorganization, including related integration issues, and (vi) the susceptibility of our industry and the markets addressed by our, and our customers', products and services to economic downturns as a result of natural disasters, epidemics, pandemics or other widespread illness, including coronavirus (or COVID-19), and (vii) other risks and uncertainties identified in our public filings with the Securities and Exchange Commission, including those listed under the "Risk Factors" and "Forward-Looking Statements" sections of our Annual Report on Form 20-F for the year ended March 31, 2024. The company assumes no obligation to update any information contained herein.