

# Eli Lilly Issues Voluntary Nationwide Recall of One Lot of Glucagon<sup>®</sup> Emergency Kit Due to Loss of Potency

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Eli Lilly and Company (Lilly) is voluntarily recalling lot D239382D, expiration April 2022, of Glucagon Emergency Kit for Low Blood Sugar (glucagon for injection, 1 mg per vial; diluent for glucagon, 1 mL syringe), to the consumer (user) level. Lilly is recalling lot D239382D to the patient level because of a product complaint that the vial of glucagon was in *liquid form* instead of the *powder form*. The firm's investigation indicates that the liquid in this glucagon vial could be related to the manufacturing process. The use of the liquid form of this product may fail to treat severe low blood sugar due to loss of potency.

**Risk Statement:** Severe hypoglycemia in patients with diabetes, if not reversed, can potentially cause adverse health consequences ranging from transient, minor complaints to neurological damage, seizures, and even death, if not promptly treated. Associated with the one product complaint, it was reported to Lilly that the involved patient experienced lack of drug effect and also reported subsequent seizures.

Glucagon Emergency Kit is used as an anti-hypoglycemic agent and a gastrointestinal motility inhibitor indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes mellitus. The product is packaged in a kit containing 1 mg of freeze-dried (lyophilized) product in a 3 mL vial and a pre-filled diluent syringe. **The recalled Glucagon Emergency Kit, NDC 00002-8031-01, lot is D239382D, and the expiration date is April 2022 (label expiry date: 04 2022).** The lot number can be found on the label of the kit as well as the vial (refer to the photos linked below – Appendix A). The lot was distributed nationwide to wholesalers and retailers.

Lilly is notifying its distributors and customers by written communication and is arranging for return and replacement of all recalled products. Wholesalers and distributors with an existing inventory of Glucagon Emergency Kit lot D239382D should cease distribution and quarantine the product immediately.

## Instructions for Wholesalers and Pharmacists

If you have distributed the recalled product, please notify any accounts or additional locations which may have received product from the recalled lot from you. Please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request they immediately cease distribution of the product and promptly contact Sedgwick at 877-907-7032 (Interactive Voice Recording), 877-884-9410 (Fax), or [elililly7484@sedgwick.com](mailto:elililly7484@sedgwick.com) (Monday through Friday 8 am to 5 pm ET) to obtain a Business Reply Card (BRC) to initiate the return process.

## Instructions for Consumers

Consumers in possession of Glucagon Emergency Kit lot D239382D should contact The Lilly Answers Center at 1-800-LILLYRX (1-800-545-5979) for return and replacement instructions for the product (Monday through Friday, 9 am to 7 pm EST) and should contact their healthcare provider (HCP) for guidance. Consumers should contact their physician or HCP if they have experienced any problems that may be related to taking or using this product.

Adverse reactions or quality problems experienced with the use of this product may 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](#).
- Regular Mail or Fax: [Download form](#) 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 conducted with the knowledge of the United States Food and Drug Administration (FDA).

Link to FDA recall notification: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/eli-lilly-and-company-issues-voluntary-nationwide-recall-one-lot-glucagonr-emergency-kit-due-loss>

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## Company Contact Information

### Consumers:

The Lilly Answers Center  
1-800-545-5979

### Media:

Gregory A. Kueterman  
317-432-5195  
[kueterman\\_gregory\\_andrew@lilly.com](mailto:kueterman_gregory_andrew@lilly.com)

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## Product Photos

Click [here](#) for product photos.