



Eli Lilly Canada Inc.

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## **Eli Lilly Canada Inc. Issues Voluntary Recall of a Single Lot of GLUCAGON (Lot D239382A, DIN 02243297) Due to Potential Loss of Potency**

**TORONTO, ON September 25, 2021** – Eli Lilly Canada is voluntarily recalling lot (D239382A) of GLUCAGON (Glucagon for Injection, 1 mg per vial; Diluent for Glucagon, 1 mL syringe), to the retail level. This recall is based on a single patient level product complaint report that a vial of GLUCAGON was in liquid form instead of the powder form. Lilly’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 (severe low blood sugar) 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 reported subsequent seizures.

GLUCAGON is used as an anti-hypoglycemic agent indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes mellitus on insulin and a gastrointestinal motility inhibitor indicated as a diagnostic aid in the radiologic examination of the gastrointestinal tract. The usual product is packaged in a kit containing 1 mg of freeze-dried product in a 3 mL vial and a pre-filled diluent syringe. The affected GLUCAGON lot is D239382A (DIN 02243297), and the expiration date is May 2022 (label expiry date: 2022-MA-10). The lot number can be found on the label of the kit as well as the vial. The lot was distributed nationwide to wholesalers and retailers.

Lilly is deeply committed to manufacturing high-quality medicines for patients who need them, and the safety and quality of our products is our highest priority. We take our obligations seriously and have rigorous quality systems in place to ensure compliance with stringent regulatory requirements.

**Wholesalers and Distributors with an existing inventory of GLUCAGON lot D239382A, should cease distribution and quarantine the product immediately.**

**Pharmacists, please reach out to your patients who have been dispensed this lot, and please work with your wholesaler contact for instructions and details about how to manage returns and order replacement product.**

**For patients, please contact your pharmacist for instructions and details about how to return your recalled product, and how to obtain a replacement.**

For any questions regarding this recall contact Lilly’s Customer Response Centre at 1-888-545-5972. Hours of operation are Monday- Friday, 9AM – 5PM EST, voicemail is set-up and will be monitored for



any inquires. Consumers should contact their physician or healthcare provider 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 Health Canada to the Canada Vigilance Program by reporting online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect), calling toll-free at 1-866-234-2345, or by completing a Canada Vigilance Reporting Form and faxing toll-free to 1-866-678-6789 or mailing to Canada Vigilance Program, Health Canada, Postal Locator 0701D, Ottawa, Ontario, K1A 0K9.

### **About Lilly Canada**

Eli Lilly and Company is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by Colonel Eli Lilly, who was committed to creating high quality medicines that meet people's needs, and today we remain true to that mission in all our work. Lilly employees work to discover and bring life-changing medicines to people who need them, improve the understanding and management of disease, and contribute to our communities through philanthropy and volunteerism.

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