

TYPE I URGENT "DRUG RECALL"

Eli Lilly Canada Inc.
Glucagon
Lot D239382A

September 25, 2021

Dear Customer:

Eli Lilly Canada Inc. is voluntarily recalling to the retail level one specific lot of Glucagon in cooperation with Health Canada. The recall extends to lot **D239382A**.

The following table lists the product label and information for the lot impacted by this recall.

Affected Product:

Product Name	Product Code	DIN	UPC	Dosage and Form	Lot Number	Expiration Date
Glucagon	MS8085001CA	02243297	773007808503	1 mg/vial Powder for Solution	D239382A	2022-MA-10

Eli Lilly Canada Inc. is voluntarily recalling lot D239382A, Expiration May 2022, of Glucagon for Low Blood Sugar (Glucagon for Injection, 1 mg per vial; Diluent for Glucagon, 1 mL syringe), to the retail level. Lilly is recalling lot D239382A to the patient level because of a product complaint reporting 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.

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.

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.

The Eli Lilly Canada Inc. Distribution period of lot D239382A is from February 1, 2021 to September 17, 2021.

It is important that you carefully follow these recall instructions:

- 1. IMMEDIATELY** reply to this notice via email at **GROUP_CA_QC@LILLY.COM** or fax at **416-699-7253** to confirm receipt of the recall notice no later than **Monday September 27, 2021**
- Examine your inventory for the recalled lot number and place all product with the lot number listed above on hold and segregate into a restricted area.
- Stop distributing the lot **IMMEDIATELY**.
- For patients who had Glucagon lot D239382A dispensed to them after February 1, 2021:
 - Please provide a copy of the attached Patient letter to communicate recall details.
 - If patient returns a Glucagon lot D239382A, please quarantine the recalled product.
 - Please arrange for replacement product with your supplier (wholesaler/distributor or CPDN)
- Carry out a physical count and complete the attached Fax Back Form **IMMEDIATELY** to advise Eli Lilly Canada Inc. of your on-hand inventory but no later than **September 30, 2021**
- Return the affected product with the recalled lot number to your original supplier (wholesaler/distributor or CPDN) as per their instructions as a separate return from other product no later than **November 8, 2021**
- Eli Lilly Canada Inc. will provide credit to your supplier whom, in turn, will provide you with a credit.

Reimbursement Information:

- Reimbursement will be in the form of a credit at the current Lilly selling price in effect at the time of the recall plus applicable mark-up, if any. Only the affected lot number will be given credit.

Please be certain to carefully review your lot numbers and return only the affected lot of **Glucagon** listed in the table of Affected Product.

Your immediate attention to the above instructions is greatly appreciated.

Adverse reactions or quality problems experienced with the use of this product may be reported to Lilly Canada Inc. at (phone) 1-88-545-5972 or (fax) 1-88-898-2961 or Health Canada to the Canada Vigilance Program by reporting online at 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.

We regret any inconvenience caused by this recall. If you require any assistance, please contact the Eli Lilly Canada Customer Response Centre at (phone) 1-888-545-5972 or (fax) 1-888-898-2961.

Eli Lilly Canada Inc. thanks you for your cooperation and assistance.

Sincerely,

Sandra Usik
Associate Vice President, Regulatory Affairs, Quality and Safety
Eli Lilly Canada Inc.

URGENT "DRUG RECALL"

Eli Lilly Canada Inc.
Glucagon
Lot D239382A

URGENT FAX BACK

TO:	Eli Lilly Canada Inc.
Fax:	416-699-7253
Email:	GROUP_CA_QC@LILLY.COM
Phone:	1-888-545-5972
Subject:	Product Recall

Please indicate the number of packages per lot you currently have in stock in the "Quantity on Hand" Column. If no stock is on hand, mark "0" beside the corresponding lot number.

Product Name	DIN	UPC	Lot Number	Expiration Date	Quantity on Hand
Glucagon	02243297	773007808503	D239382A	2022-MA-10	

Customer Name:	
Address:	
FAX Number:	
Phone Number:	

Authorized person
(print name)

Signature

Date

Fax the completed form to **416-699-7253** or email to **GROUP_CA_QC@LILLY.COM** no later than **September 30, 2021**

Return all affected lots and a copy of this form to your supplier (wholesaler/distributor or CPDN) as instructed