

TYPE I URGENT “DRUG RECALL”

Eli Lilly Canada Inc.
Glucagon
Lot D239382A

September 25, 2021

Dear Wholesaler:

Eli Lilly Canada Inc. is voluntarily recalling to the retail/pharmacy 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/pharmacy 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:

- IMMEDIATELY** reply to this notice via email at **GROUP_CA_QC@LILLY.COM** 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**.
 - If you have further distributed this lot, please notify your customers using the “Dear Customer” letter provided.
 - Please provide Lilly with a list of customers the affected product was distributed to no later than **September 28, 2021**.
 - Please maintain an accurate record of the affected product that you will be returning on behalf of your customers.
- Complete the attached Fax Back Form **IMMEDIATELY** to advise Eli Lilly Canada Inc. of your on-hand warehouse inventory but no later than **September 28, 2021**.
- Return the affected product with the recalled lot number to Stericycle no later than **November 15, 2021**.
 - Segregate the recalled lot from other Wholesaler returns.
 - Customer returns are to be fully segregated from warehouse inventory returns and should be returned on separate debit memos. No other product should be included with the recalled lot return.
 - Include the correct identifier as a reference on your debit memo and use the same identifier as your RMA authorization number:

Identifier	Description
“Recall Warehouse”	To identify returned product from wholesaler warehouse purchased at Lilly list price
“Recall Retail”	To identify returned product from retail pharmacy customers and patients
“Recall GPO”	To identify returned product from GPO members
“Recall GPO Warehouse”	To identify returned product from wholesaler warehouse purchased at GPO contract prices

Reimbursement Information:

1. Reimbursement will be in the form of a credit at the current Lilly selling price in effect at the time of the recall. Only the affected lot number will be given credit.
2. Please provide your customers with credit for the affected lots returned.

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.

We regret any inconvenience caused by this recall. If you require any assistance, please contact the Eli Lilly Canada at (email) lillycanadaorders@lilly.com or (phone) 416-693-3815.

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.

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URGENT FAX BACK

TO:	Eli Lilly Canada Inc.
Fax:	416-699-7253
Email:	GROUP_CA_QC@LILLY.COM
Phone:	416-693-3815
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	

Note: Please attach a list of customers that the affected product was distributed to if not already provided.

Wholesaler 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 28, 2021**

Return affected lot and a copy of this form to:

Stericycle
76 Wentworth Court
Brampton, ON L6T 5M7
Tel: 1-877-474-3778

Attention:
Eli Lilly Canada Inc.
c/o Stericycle ULC