



URGENT: DRUG RECALL

June 23, 2026

On behalf of Lupin Pharmaceuticals Inc.
Inmar Rx Solutions, Inc.,
Attn: Recall Coordinator,
One West Fourth Street, Suite 500 Winston Salem, NC 27101.

Dear Healthcare Partner,

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a **voluntary recall** of 7 lots of Glucagon Emergency Kit for Low Blood Sugar at the **wholesale** level.

These drug product lots are being recalled due to out-of-specification (OOS) results observed in the gliding force parameter of the **Diluent for Glucagon** during long-term stability studies of batches **WB00009** and **WB00015**.

All other functional tests and chemical quality attributes were found to be within established acceptance criteria.

Based on the Health Hazard Assessment conducted, an increase in gliding force may result in additional effort being required to expel the diluent. As the diluent remains fully contained and sterile, there is no risk of incorrect dose following the proper reconstitution. Accordingly, there is no direct risk to the patient's safety and health hazards associated with this issue is unlikely.

Glucagon Emergency Kit for Low Blood Sugar (Kit NDC: 70748-311-01) contains one Glucagon for Injection USP, 1 mg per vial (NDC: 70748-309-01) and one Diluent for Glucagon, 1mL syringe (NDC: 70748-310-01) for reconstitution:

Strength	NDC	Pack Size	Description
1 mg per vial	70748-309-01	1 each	White lyophilized cake or powder packaged in clear glass vial with grey rubber stopper and grey aluminum flip- off seal.
1 mL per syringe	70748-310-01		Clear, colorless solution free from visible particulate matter filled in 1.5 mL prefilled syringe.



Lupin Pharmaceuticals, Inc.

Glucagon Emergency Kit Batches details:

Kit Batch (NDC: 70748-311-01)	Kit Expiry	Glucagon for Injection USP, 1 mg per vial Batch (NDC:70748-309-01)	Diluent for Glucagon, 1mL syringe Batch(es) (NDC:70748-310-01)
WB00010	Jan 2027	WB00007	WB00009*
WB00017	Feb 2027	WB00013	WB00015*
WB00019	Feb 2027	WB00014	WB00018
WB00070	Jun 2027	WB00068	WB00071
WB00077	Jul 2027	WB00074	WB00091
WB00078	Jul 2027	WB00075	WB00071 & WB00091
WB00130	Nov 2027	WB00128	WB00120 & WB00121

*Batches that reported an OOS during long term stability studies.

See enclosed product label(s) for ease of identifying the product.

The recalled lots were distributed nationwide to wholesalers, distributors, supermarkets, pharmacies and mail order pharmacies between August 2025 and June 2026.

A COMPLETE PACKAGE OF INFORMATION INCLUDING A REPLY FORM WILL BE MAILED WITHIN (5) BUSINESS DAYS. THE REPLY FORMS SHOULD BE RETURNED TO INMAR Rx SOLUTIONS, INC. THROUGH MAIL/EMAIL/FAX. ONCE RECEIVED AN RA AND NEEDED BOX LABELS WILL BE PROVIDED.

Upon receipt of this packet, please take the following actions:

Please complete and return the enclosed response form as soon as possible and return via one of the following methods.

Fax: 817-868-5362

Email: rxrecalls@inmar.com

Address: Inmar Rx Solutions, Inc., Attn: Recall Coordinator – One West Fourth Street, Suite 500 Winston Salem, NC 27101.

If you have any questions about this event or the product return process, please contact Inmar Rx Solutions, Inc at 866-281-0382 between office hours of 9 AM to 5 PM EST, Monday through Friday.

1. **Wholesalers/Distributors** – Immediately examine your inventory, quarantine and discontinue distribution of this lot.
2. **Distributors** – Complete the enclosed Business Response Form even if you do not have any product on hand.

**5801 Pelican Bay Boulevard, Suite 500, Naples, Florida, USA 34108 Tel: 239-316-1900
www.lupin.com/us**



Lupin Pharmaceuticals, Inc.

3. **Distributors** – If you have units of the affected lot in inventory, please contact Inmar Rx Solutions, Inc. at 866-281-0382 to receive a Business Recall Response form or acquire it from clsnetlink.com.
4. Business Recall Response Form can be submitted by any of these methods.
Fax: 817-868-5362
Email: rxrecalls@inmar.com
Address: Inmar Rx Solutions, Inc., Attn: Recall Coordinator – One West Fourth Street, Suite 500 Winston Salem, NC 27101.
5. **Distributors/Wholesalers**– Return recalled product lot to Inmar Rx Solutions, Inc. as instructed in recall/return packet.
6. **Distributors** – **You do not need to notify your customers of this event.**

Upon receipt of the complete BRRF, a return kit will be sent including an RA form and necessary box labels.

This recall should be carried out to the **Wholesale** level.

We appreciate your immediate attention to this matter.

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

Sincerely,

Jigar Thakkar Digitally signed by Jigar Thakkar
Date: 2026.06.23 08:53:13 -04'00'

Jigar Thakkar
Manager, Quality Assurance



Lupin Pharmaceuticals, Inc.

Label (s):

a) Glucagon Emergency Kit for Low Blood Sugar (Kit NDC: 70748-311-01):

This kit contains:
 1 single dose vial of glucagon for injection, USP: 1 mg glucagon and 49 mg lactose; hydrochloric acid may have been added to adjust the pH of glucagon
 1 syringe of diluent for glucagon: 12 mg/mL glycerin, water for injection, and hydrochloric acid

Usual Dose: 1 mg subcutaneously, intramuscularly, or intravenously for adults and pediatric patients weighing more than 20 kg.
 For smaller pediatric patients, see enclosed insert.

NON-RETURNABLE

Manufactured for:
Lupin Pharmaceuticals, Inc.
 Naples, FL 34108
 United States

Manufactured by:
Lupin Limited
 Nagpur - 441108, INDIA

M.L. No.: MH/103164

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NDC 70748-311-01

Glucagon Emergency Kit for Low Blood Sugar

Glucagon for Injection USP, 1 mg per vial

Diluent for Glucagon, 1 mL syringe

Rx only
 LUPIN®

Must reconstitute vial contents with diluent.

IMPORTANT- Read the enclosed insert carefully for directions before using.
PHARMACISTS- Please detach 'INFORMATION FOR THE USER' and give to the patient.

DO NOT REMOVE PLASTIC CLIP FROM THE ACCOMPANYING SYRINGE.
 Mix immediately before use.
 Add the entire contents of the accompanying syringe into the Glucagon vial.
 Mix well and gently withdraw the entire contents of the vial back into the syringe.

Before Reconstitution: Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F) [see USP Controlled Room Temperature].

Discard unused portion.

NDC 70748-311-01

Glucagon Emergency Kit for Low Blood Sugar

Glucagon for Injection USP, 1 mg per vial

Diluent for Glucagon, 1 mL syringe

Rx only
 LUPIN®

Must reconstitute vial contents with diluent.

NVZ

Glucagon for Injection USP, 1 mg per vial
 Diluent for Glucagon, 1 mL syringe
Glucagon Emergency Kit for Low Blood Sugar



Lupin Pharmaceuticals, Inc.

b) Glucagon for Injection USP, 1 mg per vial (NDC: 70748-309-01):

NDC 70748-309-01

Glucagon for Injection, USP

1 mg per vial

Single-Dose Vial-Discard Unused Portion
For intramuscular, subcutaneous or intravenous injection.
Reconstitute with the enclosed diluent prior to use.

Rx only
LUPIN®

Contains: 1 mg glucagon, 49 mg lactose. Hydrochloric acid may have been added to adjust pH.

M.L. No.: MH/103164

Manufactured for:
Lupin Pharmaceuticals, Inc.

275723



EXP

Lot

18 x 10 mm

c) Diluent for Glucagon, 1mL syringe (NDC: 70748-310-01):

N
3 7074831001 4

Manufactured for:
Lupin Pharmaceuticals, Inc.
M.L. No.: MH/103164
276791

0.5 mg 1 mg

NDC 70748-310-01
Diluent
for Glucagon for Injection, USP
1 mL per syringe
For drug diluent use only

1 mL

Lot EXP

5801 Pelican Bay Boulevard, Suite 500, Naples, Florida, USA 34108 Tel: 239-316-1900

www.lupin.com/us



N131495 RCL166-26

Lupin Pharmaceuticals, Inc.

RECALL

Glucagon Emergency Kit

(Glucagon for Injection USP 1mg/Vial with Diluent for Glucagon) Pack Size 1's

Wholesale Level

6/23/2026

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Customer Name:		DEA#:
<i>DEA # is required, if it is not provided, the processing of your form will be delayed.</i>		
Address:		
City:	State:	Zip:
Contact Name (Please Print):		
Telephone#:	Email:	
Contact Signature:	Date:	
DEBIT MEMO# (If unsure, leave blank):		

Wholesaler Information if not directly purchased from Lupin:

Wholesaler Name:		DEA#:
City:	State:	Zip:

I have checked my stock and communicated to my customers at the appropriate level:

- I do not have any stock of the recalled items. **OR**
- I have quarantined and listed in the box below the quantity of recalled units and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s). Please indicate the # of needed box labels_____.

Product Name	NDC#	Lot#	Expiration Date	Total Full Vials	Total Partial Vials
Glucagon Emergency Kit (Glucagon for Injection USP 1mg/Vial with Diluent for Glucagon) Pack Size 1's	70748-311-01	WB00010	1/31/2027		
		WB00017	2/28/2027		
		WB00019	2/28/2027		
		WB00070	6/30/2027		
		WB00077	7/31/2027		
		WB00078	7/31/2027		
		WB00130	11/30/2027		

If you have any questions regarding this form or product return please contact Inmar at 866-281-0382 Office hours 9am to 5pm EST Mon thru Fri.

Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com

N131495 RCL166-26