Lupin Pharmaceuticals, Inc.

URGENT: MARKET WITHDRAWAL-WHOLESALE LEVEL

August 10, 2026

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

Dear Healthcare Partner,

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a **voluntary market withdrawal** of lot SB00840, expiry 11/2027 of Diazepam Rectal Gel CIV 20 mg to **wholesale level.**

This drug product lot is being withdrawn from the market due to an expiration date disparity reported between the Diazepam Rectal Gel CIV kit and lubricating jelly supplied as a component of the kit (lubricating jelly expiry date: 10/31/2027).

No actual product quality or patient impact was identified, as both the Diazepam Rectal Gel product and lubricating jelly packets are well within their labeled expiration periods. A potential future impact exists, if affected kits remain in use after the lubricating jelly packet expiration date.

Diazepam Rectal Gel (Kit NDC:43386-281-01) is supplied as:

Strength	NDC	Pack Size	Description
20 mg	43386-281-01	Kit (contains 2 syringes of 20 mg each)	Diazepam rectal gel rectal delivery system is a non-sterile, prefilled, unit dose, rectal delivery system. Tip length of the rectal delivery system is 4.4 cm. Each Twin Pack contains two diazepam rectal gel delivery systems, two packets of lubricating jelly, and administration and disposal instructions available on the bottom of the package. Diazepam rectal gel is also packed with instructions for caregivers upon receipt from pharmacy. Description of Gel: Non-sterile, Clear pale-yellow rectal gel.

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

The withdrawn lot was distributed nationwide to wholesalers, distributors, and supermarkets between January 2026 and March 2026.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., 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 855-261-5353 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.
3. **Distributors** – If you have units of the affected lot in inventory, please contact Inmar Rx solutions, Inc. at 855-261-5353 to receive a Business Response form or acquire it from clsnetlink.com.
4. Business Response Form can be submitted by any of these methods.
   Fax: 817-868-5362
   Email: rxrecalls@inmar.com
   Address: Inmar Rx Solutions, Inc., One West Fourth Street, Suite 500 Winston Salem, NC 27101.
5. **Distributors/Wholesalers**– Return withdrawn product lot to Inmar Rx Solutions, Inc. as instructed in withdrawn/return packet.
6. **Distributors – You do not need to notify your customers of this event.**

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

This withdrawal should be carried out to **Wholesale level**.

We appreciate your immediate attention to this matter.

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

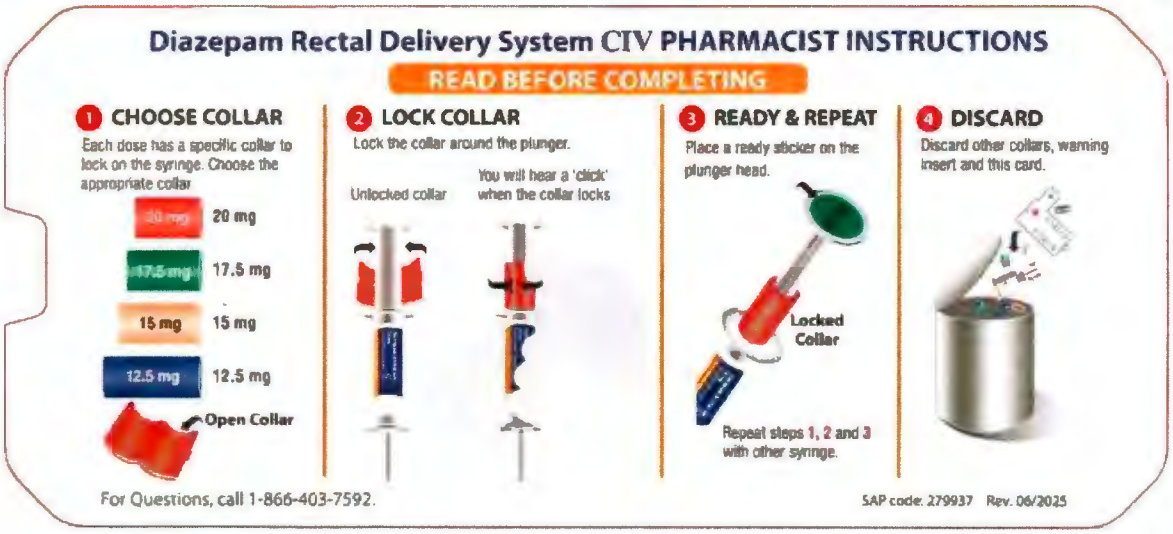
Sincerely,

Jigar Thakkar Digitally signed by Jigar Thakkar
Date: 2026.08.10 13:46:54 -04'00'

Jigar Thakkar
Manager, Quality Assurance

Label (s):

a) Diazepam Rectal Gel (Kit NDC:43386-281-01):



b) <u>Diazepam Rectal Gel Syringe label</u> (NDC: 43386-281-03):

N131510 RCL201-26

Lupin Pharmaceuticals, Inc.

MARKET WITHDRAWAL

Diazepam Rectal Gel 20mg CIV

Wholesale Level

8/10/2026

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

Customer Name: | DEA#:

DEA # is required, if it is not provided, the processing of your form will be delayed.

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 withdrawn 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 Kits	Total Partial Kits
Diazepam Rectal Gel 20mg CIV	43386-281-01	SB00840	11/30/2027		

If you have any questions regarding this form or product return please contact Inmar at 855-261-5353 Office hours 9am to 5pm EST Mon thru Fri.

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

N131510 RCL201-26