

**MARKET WITHDRAWAL LETTER****Diastat® (diazepam rectal gel)/Diastat® AcuDial™ (diazepam rectal gel)  
Rectal Delivery System 10 mg and 20 mg - Market Withdrawal**

September 04, 2025

NageswaraRao Guthula  
Sr. Director, External Manufacturing Quality-US  
Bausch Health US, LLC  
400 Somerset Corporate Boulevard  
Bridgewater, NJ 08807

Dear Valued Customer:

Bausch Health US, LLC is conducting a voluntary market withdrawal for Diastat® (diazepam rectal gel)/Diastat® AcuDial™ (diazepam rectal gel) Rectal Delivery System 10 mg and 20 mg (NDC: 68682-652-20 and 68682-655-20). This market withdrawal is being made with the knowledge of the Food and Drug Administration.

This market withdrawal is being initiated because the lubricating jelly packet supplied with the Diastat (Diazepam) Rectal Gel Delivery System has an expiry date that is earlier than the drug product expiry date. There is no issue related to the quality of the drug product up to the assigned expiry date except with the expiry date of the lubricating jelly packet. The issue with the expiry date on the lubricating jelly packets is detectable as it is printed on the packets. Please see the enclosed product images for ease of identification of the product.

Bausch Health intends to carry out a phased approach for market withdrawal at the pharmacy level based on the expiry date of the lubricating jelly packets. This letter serves as a notification that the finished product lots listed in Table 1 below are included within the scope.

**Table 1**

Product Name	NDC #	Lot#	Product Exp Date	Jelly Pack Exp Date	Distribution Dates
Diazepam Rectal Gel, 10mg	68682-652-20	SKCH	10/31/2026	<b>11/30/2025</b>	2022 - 2025
		SKCG	9/30/2026	<b>11/30/2025</b>	2022 - 2025
Diazepam Rectal Gel, 20mg	68682-655-20	SKCR	9/30/2026	<b>11/30/2025</b>	2022 - 2025

Immediately examine your inventory. If you have the affected lot numbers of the withdrawn product in your stock, please discontinue further distribution, quarantine the affected product, and return all units to: Inmar Rx Solutions, 3845 Grand Lakes Way, Grand Prairie, TX 75050, the firm managing this voluntary product withdrawal on behalf of Bausch Health.

Please complete the enclosed "PRODUCT WITHDRAWAL RESPONSE FORM" and fax it to Inmar at 1-817-868-5362 or email it to [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com). Even if you do not possess any inventory of the lot being withdrawn, we would appreciate if you could still fill out and return the "PRODUCT WITHDRAWAL RESPONSE FORM". Upon

Enclosure(s): 1

**MARKET WITHDRAWAL LETTER****Diastat® (diazepam rectal gel)/Diastat® AcuDial™ (diazepam rectal gel)  
Rectal Delivery System 10 mg and 20 mg - Market Withdrawal**

receipt of the product withdrawal response form, a replacement for the returned product will be provided, followed by the return of the product.

In addition, if you have further distributed these lot numbers, please identify them and notify your customers. A copy of this market withdrawal notification letter can be sent to the customers.

Your assistance is appreciated and necessary to prevent further distribution of these lots. We apologize for any inconvenience this may cause.

If you have any questions, please contact Bausch Health US, LLC Customer Care via phone at 800-321-4576 (opt 2 / inquiries) or by email at [customercare@bauschhealth.com](mailto:customercare@bauschhealth.com).

Sincerely,



04 SEP 2025

NageswaraRao Guthula

Sr. Director, External Manufacturing Quality-US

## Enclosure 1 Product Images Diastat® (diazepam rectal gel)/Diastat® AcuDial™ (diazepam rectal gel) Rectal Delivery System

Open Kit with a view of the Syringes and contents



Lubricating Jelly Pack



Top View of Twin Pack



Label with Lot Number

**PRODUCT WITHDRAWAL RESPONSE FORM**  
**Diastat® (diazepam rectal gel)/Diastat® AcuDial™ (diazepam rectal gel)**  
**Rectal Delivery System 10 mg and 20 mg - Market Withdrawal**  
**Retail Pharmacy Level – 09/04/2025**

RCL216-25 N131354

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

Customer Name:		DEA#:
<b>DEA # is required, if it is not provided, the processing of your form will be delayed.</b>		
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 Bausch Health:**

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

**Please review and acknowledge (X) on one of the statements below that applies to your facility:**

- ☐ I have checked my stock and do NOT have any inventory.
- ☐ I have checked my stock and have quarantined inventory. Please fill out the table below with the quantity of withdrawn units to be returned to Inmar.

Item Description	NDC #	Lot#	Product Exp Date	Jelly Pack Exp Date	Cases	Partial Cases	Total Number of Twin Packs
Diazepam Rectal Gel, 10mg	68682-652-20	SKCH	10/31/2026	11/30/2025			
		SKCG	9/30/2026	11/30/2025			
Diazepam Rectal Gel, 20mg	68682-655-20	SKCR	9/30/2026	11/30/2025			

Upon receipt of this Response Form, Inmar, will issue return authorization label(s) Please indicate the # of needed box labels \_\_\_\_\_.

If you have any questions regarding this form or product return, please contact Inmar at 888-676-9712.  
Office hours are 9am to 5pm EST, Mon thru Fri.

**Please complete, sign, and return this form to:**

**Fax:** 1-817-868-5362    **Email:** [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com)    **Phone:** 1-888-676-9712

**Mailing Address:** 3845 Grand Lakes Way, Grand Prairie, TX 75050

RCL216-25 N131354