

Bausch Health US, LLC is conducting a voluntary market withdrawal for **Diastat® (diazepam rectal gel)/Diastat® AcuDial™ (diazepam rectal gel) Rectal Delivery System 2.5 mg, 10 mg and 20 mg** (NOC: 68682-650-20, 68682- 652-20, 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.

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..

Table 1

Product Name	NDC#	Lot#	Product Exp Date	Jelly Pack Exp Date	Distribution Dates
Diazepam Rectal Gel, 2.5mg	68682-650-20	SCED	3/31/2025	10/31/2024	5/21/2021- 7/29/2021
Diazepam Rectal Gel, 10mg	68682-652-20	RADH-1	1/31/2025	6/30/2024	09/22/2020 - 11/30/2020
		SGCW-1	7/31/2026	10/31/2024	9/17/2021- 9/29/2021
		SCED-1	3/31/2026	10/31/2024	5/21/2021- 7/29/2021
Diazepam Rectal Gel, 20mg	68682-655-20	SHCR	8/31/2026	10/31/2024	11/10/2021- 01/26/2022
		RODD	5/31/2025	10/31/2024	4/27/2021- 9/13/2021
		RBBM-1	02/28/2025	10/31/2024	1/5/2021- 4/29/2021