

Drug Recall

DATE OF RECALL: May 3, 2023

DRUG NAME: Dianeal Peritoneal Dialysis Solution with 1.5% Dextrose

RECALLING FIRM: Baxter Healthcare Corporation.

REASON FOR RECALL: This recall was issued due to Lack of Assurance of Sterility: Potential presence of leaks originating from the Luer component.

FDA LINK: N/A

OTHER DETAILS: N/A

RECALLED PRODUCT:

Product Description	NDC Number	Lot Number	Expiration Date
Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose, packaged in 5000 mL per Ambu-Flex II Container bag	00941-0409-07	Y406130	10/31/2024
Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose, packaged in 6000 mL per Ambu-Flex II Container bag	00941-0409-01	Y406314 Y406314A Y406963 Y407199	10/31/2024 10/31/2024 10/31/2024 10/31/2024
Dianeal PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose, 3000 mL per Ambu-Flex II Container bag	00941-0411-04	Y405201	10/31/2024