



Recall of Sodium Bicarbonate, Midazolam, and ELCYS (cysteine hydrochloride) Injection Products by Exela

Effective Date: 10/25/2023

On October 25, 2023, Exela announced a voluntary recall of several lots of sodium bicarbonate injection, one lot of midazolam in sodium chloride injection and one lot of ELCYS (cysteine hydrochloride) injection because of particulate matter identified as silicone.

Per Exela, administration of an injectable product that contains silicone particulates may cause local irritation or swelling. If the particulate matter reaches the blood vessels it can travel to various organs and lead to life-threatening events.

You are receiving this notice as our records indicate within the past 60 days you have dispensed the above product(s) to a GA Medicaid FFS member. Please check your inventory to determine if you stock the affected product and notify any affected patients if possible.

You can call Exela by phone at **828-341-6118** (9:00 a.m. – 5:00 p.m. EST, Monday through Friday) or by email at **recall@excel.us** for more information.

Sodium Bicarbonate, Midazolam and ELCYS Injection Products Recalled by Exela

Product Description	NDC Number	Lot Number (Exp Date)
Sodium bicarbonate 8.4% injection, 50 mEq/50 mL, 50 mL single dose vial	Exela brand: Carton: 51754-5001-5 51754-5001-4 Vial: 51754-5001-1	P0001429 (11/2023) P0001900 (8/2024) P0001902 (8/2024) P0001903 (9/2024) P0001909 (9/2024) P0001945 (9/2024) P0002002 (11/2024) P0002052 (12/2024)
	Civica brand Carton: 72572-740-20 Vial: 72572-740-01	P0001912 (8/2024)
Midazolam in 0.8% sodium chloride injection, 100 mg/100 mL, 100 mL single dose vial	Carton: 51754-2131-4 Vial: 51754-2131-1	10001088 (7/2024)
ELCYS (cysteine hydrochloride) injection, 500 mg/10 mL, 10 mL single dose vial	Carton: 51754-1007-3 Vial: 51754-1007-1	10000798 (3/2025)

Reference:

FDA Safety Alert. Exela Pharma Sciences, LLC Issues Voluntary Nationwide Recall of 8.4% Sodium Bicarbonate Injection, USP, 50 mEq/50 mL, Midazolam in 0.8% Sodium Chloride Injection 100 mg/100 mL, and ELCYS (cysteine hydrochloride Injection), USP 500 mg/10 mL Due to the Presence of Particulate Matter. FDA website. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/exela-pharma-sciences-llc-issues-voluntary-nationwide-recall-84-sodium-bicarbonate-injection-usp-50>. Accessed October 26, 2023.

Thank you for your continued support.