Exela Pharma Sciences – Recall of sodium bicarbonate, midazolam, and ELCYS (cysteine hydrochloride) injection products

- On October 25, 2023, Exela Pharma Sciences announced a consumer-level 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.

- The affected lots were shipped nationwide:

  - Sodium bicarbonate injection: January 18, 2022 through February 15, 2023
  - Midazolam in sodium chloride injection: July 14, 2023 through September 26, 2023
  - ELCYS: July 20, 2023 through August 1, 2023

Product Description	NDC Number	Lot Number (Exp Date)
Sodium bicarbonate 8.4% injection, 50 mEq/50 mL, 50 mL single dose vial	Exela brand: 51754-5001-5, 51754-5001-4 (carton); 51754-5001-1 (vial)	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: 72572-740-20 (carton); 72572-740-01 (vial)	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)

- Sodium bicarbonate injection, is used for the treatment of metabolic acidosis.

- Midazolam in sodium chloride injection is used for sedation.

- ELCYS injection is used for nutritional requirements per total parenteral nutrition.

- Per Exela, administration of an injectable product that contains particulate matter may result in local irritation or swelling in response to the foreign material. If the particulate matter reaches the blood vessels it can travel to various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death.

- To date, Exela has not received reports of any adverse events associated with this issue for these lots.

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- Anyone with the affected lot(s) on hand should stop distribution and return product. Patients should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

- Contact Exela by phone at **1-828-341-6118** or by email at **recall@exela.us** for more information about this recall.