

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Exela Pharma Sciences LLC is recalling nine (9) lots of 8.4% Sodium Bicarbonate Injection, USP (20 and 25 count cartons); impacted lots listed below. White particles were observed in the drug product retention samples during annual examination. Particulates can create serious health risks when administered intravenously. There have been no reports of adverse events from the administration of the drug product from the affected lots. This recall is being carried out in an abundance of caution.

This recall is being made to the Dispensing Level. Eight (8) of the nine (9) lots were distributed under Exela Pharma Sciences label and one (1) lot was distributed under Civica label. Distribution dates: 1/18/2022 - 02/15/2023. The details of the lots are provided in the table below.

Sodium Bicarbonate Injection, USP is indicated in the treatment of metabolic acidosis which may occur in severe renal disease, uncontrollable diabetes, circulatory insufficiency due to shock or severe dehydration, extracorporeal circulation of blood, cardiac arrest and severe primary lactic acidosis. Sodium bicarbonate is further indicated in the treatment of certain drug intoxications, including barbiturates (where dissociation of the barbiturate-protein complex is desired), in poisoning by salicylates or methyl alcohol and in hemolytic reactions requiring alkalization of the urine to diminish nephrotoxicity of hemoglobin and its breakdown products. Sodium bicarbonate also is indicated in severe diarrhea which is often accompanied by a significant loss of bicarbonate.

Item Description	NDC	Lot	Expire Date
8.4% Sodium Bicarbonate Injection, USP 20 vials per carton	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001429	11/2023
8.4% Sodium Bicarbonate Injection, USP 25 vials per carton	Carton: 51754-5001-4 Inner Vial: 51754-5001-1	P0001900	08/2024
8.4% Sodium Bicarbonate Injection, USP 25 vials per carton	Carton: 51754-5001-4 Inner Vial: 51754-5001-1	P0001902	08/2024
8.4% Sodium Bicarbonate Injection, USP 25 vials per carton	Carton: 51754-5001-4	P0001903	09/2024

8.4% Sodium Bicarbonate Injection, USP 25 vials per carton	Inner Vial: 51754-5001-1 Carton: 51754-5001-4	P0001909	09/2024
8.4% Sodium Bicarbonate Injection, USP 25 vials per carton	Inner Vial: 51754-5001-1 Carton: 51754-5001-4	P0001945	09/2024
8.4% Sodium Bicarbonate Injection, USP 25 vials per carton	Inner Vial: 51754-5001-1 Carton: 51754-5001-4	P0002002	11/2024
8.4% Sodium Bicarbonate Injection, USP 25 vials per carton	Inner Vial: 51754-5001-1 Carton: 51754-5001-4	P0002052	12/2024

Batches Manufactured by Exela Pharma Sciences, LLC for Civica, Inc.

Lots packaged under a Civica, Inc. Label

Item Description	NDC	Lot	Expire Date
8.4% Sodium Bicarbonate Injection, USP 20 vials per carton	Carton: 72572-740-20 Inner Vial: 72572-740-01	P0001912	08/2024