

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.

Please be advised that fourteen additional lots were identified to be added to the initial recall for Sodium Bicarbonate Injection, USP, 50mEq/50mL, 20-count carton. There have been no breakages or injuries reported regarding these lots; they are being added to the recall out of an abundance of caution. The distribution timeframe for these lots was October 26, 2021, through April 25, 2022. The impacted lots are listed below.

THIS IS A SECOND UPDATE TO THE RECALL NOTICE OF 10/04/2022. THE FIRST UPDATE WAS PROVIDED 10/20/2022. THE CURRENT UPDATE RELATES TO THE ADDITION OF FOURTEEN (14) LOTS TO THE RECALL. THERE HAVE BEEN NO COMPLAINTS OR INJURIES RELATED TO THESE LOTS.

Exela Pharma Sciences LLC is recalling an additional 14 lots of **8.4% Sodium Bicarbonate Injection, USP (20 count cartons)** to the previously recalled 49 lots bringing the total recall to 63 lots.

Exela has observed breakage of one vial during the most recent inspection of the retain samples of the fourteen lots. There have been no additional reports of injury from the field since the previous recall notice issued on October 4, 2022. There has been no evidence of sterility failure.

This recall is being carried out in an abundance of caution due to a potential safety concern with vial breakage while preparing the product for administration. The standard process of solution extraction via a syringe does not require pressurizing the vial but in some instances, the health care provider may apply pressure to the vial that can on occasion result in vial breakage.

This recall is being made to the Dispensing Level.

Item Description	NDC	Lot	Expire Date
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001178	05/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001298	08/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001301	08/2023

Item Description	NDC	Lot	Expire Date
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001313	08/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001314	08/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001317	08/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001330	09/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001442	11/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001464	09/2023

Item Description	NDC	Lot	Expire Date
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001467	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001472	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001486	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001532	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 72572-740-20 Inner Vial: 72572-740-1	P0001490	12/2023

THE PREVIOUSLY RECALLED 49 LOTS ARE LISTED BELOW:

Brand	Lot	Expire Date
Exela	P0001370	10/2023
Exela	P0001371	10/2023
Exela	P0001372	10/2023
Exela	P0001433	11/2023
Exela	P0001434	11/2023
Exela	P0001443	12/2023
Exela	P0001468	12/2023
Exela	P0001469	12/2023
Exela	P0001470	12/2023
Exela	P0001495	12/2023
Exela	P0001505	12/2023
Exela	P0001506	12/2023
Exela	P0001509	12/2023
Exela	P0001510	12/2023
Exela	P0001511	12/2023
Exela	P0001512	12/2023
Exela	P0001560	01/2024
Exela	P0001561	01/2024
Exela	P0001562	01/2024
Exela	P0001564	01/2024
Exela	P0001566	01/2024
Exela	P0001567	01/2024
Exela	P0001568	01/2024
Exela	P0001571	02/2024
Exela	P0001572	02/2024
Exela	P0001573	02/2024
Exela	P0001574	02/2024
Exela	P0001578	02/2024
Exela	P0001579	02/2024
Exela	P0001580	02/2024
Exela	P0001583	02/2024
Exela	P0001586	02/2024

Brand	Lot	Expire Date
Exela	P0001587	02/2024
Exela	P0001588	02/2024
Exela	P0001593	02/2024
Exela	P0001594	02/2024
Exela	P0001610	02/2024
Exela	P0001618	02/2024
Exela	P0001619	02/2024
Exela	P0001644	03/2024
Exela	P0001645	03/2024
Exela	P0001646	03/2024
Exela	P0001654	02/2024
Exela	P0001662	03/2024
Exela	P0001664	03/2024
Exela	P0001730	05/2024
Civica	P0001497	12/2023
Civica	P0001600	02/2024
Civica	P0001663	03/2024