COMMUNICATION

COM-2022-068

05
DECEMBER
2022

URGENT
PLEASE
REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

11/30/2022

Drug Information:

National Drug Code

EXELA BRAND: 51754-5001-05 (CARTON), 51754-5001-01 (VIAL)

CIVICA BRAND: 72572-0740-20 (CARTON), 72572-0740-01 (VIAL)

Product Description

SODIUM BICARBONATE INJECTION, USP, 8.4%, 50MEQ/50ML VIAL, 20-COUNT CARTON

Lot Number

REFER TO THE TABLE INCLUDED IN THIS NOTIFICATION.

Expiration Date

REFER TO THE TABLE INCLUDED IN THIS NOTIFICATION.

Company:

EXELA PHARMA SCIENCES, LLC (EXELA)

QUESTIONS

Call EXELA at 828-341-6118
Monday – Friday from 9:00 a.m. to 5:00 p.m. ET.

Email EXELA at recall@exela.us

Sodium Bicarbonate Injection

It is for this reason that we are notifying you that on 11.30.2022 the US Food and Drug Administration published a drug recall for the following product(s): Sodium bicarbonate injection, USP, 8.4%, 50mEq/50mL vial, 20-count carton.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Exela Pharma Sciences, LLC, is adding fourteen lots to the ongoing voluntary recall of 49 lots of sodium bicarbonate injection, USP, 8.4%, 50mEq/50mL vial, 20-count carton. A total of 63 lots are now being recalled to the consumer level. The additional lots were distributed from 10/26/2021 to 4/25/2022.

During the latest inspection of Exela's retained product from the 14 lots, one vial showed breakage, which presents the potential for flying glass injuring skin and eyes. There have been no reports of breakage or injury from the additional lots, but previously Exela received five reports of flying glass and injury among the lots involved in the first recall.

Exela is notifying its customers by e-mail and certified mail and is arranging for return and replacement of all recalled products directed to Exela.

The affected Sodium Bicarbonate Injection, USP, 8.4%, 50mEq/mL lots (covering both Exela and Civica brands) that were added to the ongoing voluntary recall are listed below.

Brand	Lot	Expiration Date
Exela	P0001178	05/2023
Exela	P0001298	08/2023
Exela	P0001301	08/2023
Exela	P0001313	08/2023
Exela	P0001314	08/2023
Exela	P0001317	08/2023
Exela	P0001330	09/2023
Exela	P0001442	11/2023
Exela	P0001464	09/2023
Exela	P0001467	12/2023
Exela	P0001472	12/2023
Exela	P0001486	12/2023
Exela	P0001532	12/2023
Civica	P0001490	12/2023

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- ext. 220. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Recall Communication Number COM-2022-068 December 2022

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Pharmacy Benefit Management
12/01/2025

REFERENCES:

1. U.S. Food and Drug Administration. (2022). Exela Pharma Sciences, LLC Expands Voluntary Nationwide Recall of Sodium Bicarbonate Injection, USP, 8.4%, 50mEq/50mL Vial, 20-Count Carton Due to Vial Breakage UPDATED November 28,2022. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/exela-pharma-sciences-llc-expands-voluntary-nationwide-recall-sodium-bicarbonate-injection-usp-84-50
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda