COMMUNICATION

COM-2023-062

26
OCTOBER
2023

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:

10/25/2023

Drug Information:

National Drug Code

Refer to the table included in the notification.

Product Description

SODIUM BICARBONATE 8.4% INJECTION

MIDAZOLAM IN 0.8% SODIUM CHLORIDE INJECTION

ELCYS™ (CYSTEINE HYDROCHLORIDE) INJECTION

Batch Number

Refer to the table included in the notification.

Expiration Date

Refer to the table included in the notification.

Company:

EXELA PHARMA SCIENCES, LLC

QUESTIONS

Call EXELA PHARMA SCIENCES, LLC at 828-341-6118 Monday – Friday from 9:00 a.m. to 5:00 p.m. ET or by email at recall@exela.us.

Sodium Bicarbonate Injection, Midazolam in 0.8% Sodium Chloride Injection and Elcys™ Injection

It is for this reason that we are notifying you that on 10.25.2023 the US Food and Drug Administration published a drug recall for the following products: Sodium Bicarbonate Injection Solution 8.4 %, Midazolam in 0.8% Sodium Chloride Injection and Elcys™ (Cysteine Hydrochloride) Intravenous Solution 500mg/10mL.

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, (Exela) is voluntarily recalling Sodium Bicarbonate Injection Solution 8.4 %, Midazolam in 0.8% Sodium Chloride Injection and Elcys™ Intravenous Solution 500mg/10mL to the consumer level. Particulate matter identified as silicone was observed during routine inspection of retained samples.

The 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.

Exela has not received any reports of adverse events related to this recall.

Recalled Lots:

Product	Lot Number	Expiration Date	NDC (s)	Distribution Dates
Sodium Bicarbonate Injection Solution 8.4 %	P0001429	11/2023	Vial - 51754-5001-1 Carton - 51754-5001-5	July 20, 2023, to August 1, 2023
	P0001900	08/2024		
	P0001902	08/2024		
	P0001903	09/2024	Vial - 51754-5001-1 Carton - 51754-5001-4	
	P0001909	09/2024		
	P0001912	08/2024		
	P0001945	09/2024	Vial - 72572-740-01 Carton - 72572-740-20	
	P0002002	11/2024		
	P0002052	11/2024		
Midazolam in 0.8% Sodium Chloride Injection	10001088	07/2024	Vial- 51754-2131-1 Carton - 51754-2131- 4	
Elcys™ Intravenous Solution 500mg/10mL	10000798	03/2025	Vial - 51754-1007-1 Carton- 51754-1007-3	

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. 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-2023-062 October 2023

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REFERENCES:

1. U.S. Food and Drug Administration. (2023). 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. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/exela-pharma-sciences-llc-issues-voluntary-nationwide-recall-84-sodium-bicarbonate-injection-usp-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.

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