COMMUNICATION

COM-2022-055

14 October 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:

10/13/2022

Drug Information:

National Drug Code

51754-5001-05, 51754-5001-01, 72572-0740-20, 72572-0740-01

Product Description

Sodium Bicarbonate Injection, USP, 8.4%, 50 mEq/50 mL

Batch Number

For the List of Batch Numbers Click: Here

Expiration Date

For the List of Expiration Dates Click: Here

Company:

Exela Pharma Sciences, LLC

CONTACT INFORMATION RETURN OF RECALLED DRUG

Call Exela Pharma at 828.341.6118 x 1017 Monday – Friday from 9:00 a.m. to 5:00 p.m. EST.

Email Exela Pharma at

recall@exela.us

Sodium Bicarbonate Injection, USP, 8.4%, 50 mEq/50 mL vial

It is for this reason that we are notifying you that on 10.13.2022 the US Food and Drug Administration published a drug recall for the following product(s): Sodium Bicarbonate Injection, USP, 8.4%, 50 mEq/50 mL vial.

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 forty-nine (49) lots of Sodium Bicarbonate Injection, USP, 8.4%, 50 mEq/50 mL vial, 20- count carton, to the consumer level. The product poses a potential safety concern with vial breakage and flying glass when pressurized while preparing the product for administration. Exela has received five (5) reports of flying glass injuring skin, eye and/or other parts. There have been no reports of sterility failures.

The vials are labeled with Exela brand and Civica brand. The Exela product (Carton NDC: 51754-5001-5; Vial NDC: 51754-5001-1) and the Civica Product (Carton NDC: 72572-740-20; Vial NDC: 72572-740-1).

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-2022-055 October 2022

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ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

REFERENCES:

1. U.S. Food and Drug Administration. (2022). Exela Pharma Sciences, LLC Issues Voluntary Nationwide Recall of Sodium Bicarbonate Injection, USP, 8.4%, 50 mEq/50 mL Vial, 20-Count Carton Due to Vial Breakage. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/exela-pharma-sciences-llc-issues-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