COMMUNICATION

COM-2024-054

9 August 2024

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:

8/8/2024

Drug Information:

National Drug Code

0264-7800-09

Product Description:

NaCL Inj 0.9% 1000ML – E8000

Lot Number

J2L763

J2L764

Expiration Date

March 31, 2025

Company:

B. Braun Medical Inc.

QUESTIONS

Call B. Braun Medical Inc. Customer Support at 800-227-2862, Monday - Friday, 8:00 am – 6:00 pm EST.

0.9% Sodium Chloride Injection USP 1000 mL

It is for this reason that we are notifying you that on 08.08.2024 the U.S. Food and Drug Administration published a drug recall for the following product(s): 0.9% Sodium Chloride for Injection USP 1000 mL in E3 containers.

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:

B. Braun Medical Inc. is voluntarily recalling two (2) lots of 0.9% Sodium Chloride for Injection USP 1000 mL in E3 containers within the United States to the consumer level. The voluntary recall has been initiated due to the potential for particulate matter and fluid leakage of the respective containers. The affected batches were inadvertently released to the market prior to the completion of the required acceptance activities for embedded particulate matter which may result in leakage. To date, there have been no customer complaints received and there have been no reports of serious injury or death associated with this issue.

Risk Statement:

There is a reasonable probability of embolic phenomena such as stroke or ischemia/infarct to other organs and possible infection if these particulates are not sterile that could lead to permanent damage or impairment of body function which would be life-threatening.

CLINICAL PEARLS

BY PHARMPIX

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- ext. 219. 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-2024-054 August 2024

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REFERENCES:

1. U.S. Food and Drug Administration. (2024). B. Braun Issues Voluntary Nationwide Recall of 0.9% Sodium Chloride for Injection USP 1000 mL in E3 Containers Due to the Potential for Particulate Matter and Leakage. Retrieved August 9,2024 from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/b-braun-issues-voluntary-nationwide-recall-09-sodium-chloride-injection-usp-1000-ml-e3-containers
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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