COMMUNICATION

COM-2024-053

7
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:

8/6/2024

Drug Information:

National Drug Code

0338-0433-04

Product Description:
Heparin Sodium 0.9% Sodium Chloride Injection

Lot Number

N008235

Expiration Date

31-Aug-2024

Company:

Baxter International Inc.

QUESTIONS

Call Baxter Healthcare Center for Service at (888)-229-0001, Monday - Friday, 7:00 a.m. – 6:00 p.m. CT.

Heparin Sodium in 0.9% Sodium Chloride Injection 2,000 Units, USP

It is for this reason that we are notifying you that on 08.06.2024 the US Food and Drug Administration published a drug recall for the following product(s): Heparin Sodium in 0.9% Sodium Chloride Injection, 2,000 units per 1,000 mL.

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:

Baxter International Inc. is voluntarily recalling one lot of Heparin Sodium in 0.9% Sodium Chloride Injection, 2,000 units per 1,000 mL to the consumer level due to the potential for elevated endotoxin levels based on issues related to the bacterial endotoxin test specific to lot number N008235. This affected lot was distributed between March 12, 2023, and August 24, 2023, to healthcare facilities, wholesalers and distributors in the United States.

Risk Statement:

Use of heparin with higher than acceptable endotoxin levels may lead to significant adverse health consequences ranging from febrile reactions to toxic shock, multi-organ failure and death. To date, Baxter has not received any reports of adverse events related to this issue.

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-2024-053 August 2024

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REFERENCES:

1. U.S. Food and Drug Administration. (2024). American Health Packaging on Behalf of BluePoint Laboratories Issues Voluntary Nationwide Recall for **Baxter Issues Voluntary Nationwide Recall of One Lot of Heparin Sodium 0.9% Sodium Chloride Injection Due to Potential for Elevated Endotoxin Levels.** Retrieved August 6,2024 from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/baxter-issues-voluntary-nationwide-recall-one-lot-heparin-sodium-09-sodium-chloride-injection-due
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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