COMMUNICATION

COM-2024-041

27
JUNE
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:

6/26/2024

Drug Information:

National Drug Code
68001-396-00
68001-396-03

Product Description:
Potassium Chloride Extended Release 750mg Capsules, 100 count and 500 count

Lot Number
Refer to the table included in the notification

Expiration Date
Refer to the table included in the notification

Company:

American Health Packaging

QUESTIONS
Call Sedgwick Inc at 1- 855-695-8564, Monday - Friday, 8:00 am – 5:00 pm EST.

Potassium Chloride Extended Release 750mg Capsules, USP

It is for this reason that we are notifying you that on 06.26.2024 the U.S. Food and Drug Administration published a drug recall for the following product(s): Potassium Chloride Extended-Release Capsules, USP (750 mg) 10 mEq K.

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:

American Health Packaging on behalf of BluePoint Laboratories is voluntarily recalling 21 batches of Potassium Chloride Extended-Release Capsules, USP (750 mg) 10 mEq K, to the consumer level. The product is being recalled because of failed dissolution.

The failed dissolution of potassium chloride extended-release capsules may cause high potassium levels, also known as hyperkalemia, which can result in irregular heartbeat that can lead to cardiac arrest. To date, the firm has not received any reports of hyperkalemia or serious adverse events from spontaneous sources related to this recall.

Recalled Lots:

Number	NDC	Product	Lot Number	Expiration Date
1.	68001-396-00	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 100 count	17221738	07/31/2024
2.	68001-396-00	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 100 count	17222494	10/31/2024
3.	68001-396-00	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 100 count	17230533	1/31/2025
4.	68001-396-00	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 100 count	17232208	9/30/2025
5.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17221823	7/31/2024
6.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17221830	7/31/2024
7.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17221831	8/31/2024
8.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17230248	12/31/2024
9.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17230253	12/31/2024
10.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17230271	12/31/2024
11.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17230796	2/28/2025
12.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17230820	2/28/2025
13.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17230825	3/31/2025
14.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17230833	3/31/2025
15.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17230840	3/31/2025
16.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17231537	6/30/2025
17.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17231540	6/30/2025
18.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 100 count	17231719	6/30/2025
19.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17231737	6/30/2025
20.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17232111	9/30/2025
21.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17232164	9/30/2025

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-2024-041 June 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 Potassium Chloride Extended-Release Capsules, USP (750 mg) 10 mEq K Due to Failed Dissolution Retrieved June 26,2024 from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/american-health-packaging-behalf-bluepoint-laboratories-issues-voluntary-nationwide-recall-potassium
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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