Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC24-029-CG
June 28, 2024

FDA announced that 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.

RECOMMENDATIONS

1. American Health Packaging on behalf of BluePoint Laboratories is notifying its wholesale and distributor customers by written letters and is arranging for return of all recalled batches. Wholesalers, distributors, and retailers that have the recalled products should discontinue distribution of the recalled product lots immediately and follow the instructions provided in the written recall letter. Wholesalers and distributors should conduct a sub-recall to retail or pharmacy customers.

2. Consumers that have Potassium Chloride Extended-Release Capsules subject to the recall should consult with their physician or health care provider before they stop using the product. Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

3. Consumers should call Sedgwick, a recall solution vendor, at 1- 855-695-8564, Monday - Friday, 8:00 am – 5:00 pm EST for return instructions and further information.

4. Review your inventory to identify existence of recalled products.

5. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

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FDA U.S. FOOD & DRUG ADMINISTRATION

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

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SUMMARY:

Company Announcement Date:	June 25, 2024
FDA Publish Date:	June 26, 2024
Product Type:	Drugs
Reason for Announcement:	Failed dissolution
Company Name:	American Health Packaging
Brand Name:	Blue Point Laboratories
Product Description:	Potassium Chloride Extended Release 750mg Capsules, 100 count and 500 count

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COMPANY ANNOUNCEMENT:

FOR IMMEDIATE RELEASE – June 25, 2024 – 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.

Risk Statement: 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. For patients who require chronic use of potassium chloride extended-release oral capsules, especially in those patients with underlying comorbidities or conditions that cause altered excretory mechanisms for potassium such as hypertension, heart failure, or renal dysfunction, there is a reasonable probability of developing hyperkalemia that may lead to a range of severity of adverse events from being asymptomatic to more severe potential life threatening adverse events of hyperkalemia such as cardiac arrythmias, severe muscle weakness, and death. To date, the firm has not received any reports of hyperkalemia or serious adverse events from spontaneous sources related to this recall.

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Potassium Chloride Extended-Release Capsules are used for the treatment of patients with low potassium (hypokalemia) and are packaged in bottles of 100-count (NDC 68001-396-00) and 500-count (NDC 68001-396-03) capsules.

The Potassium Chloride Extended-Release Capsules being recalled were distributed nationwide to wholesale, distributor, and retail outlets.

The recall includes the lot numbers and expiration dates listed below:

Sr. No	NDC	Product Name	Batch No.	Expiry 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	01/31/2025
4.	68001-396-00	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 100 count	17232208	09/30/2025
5.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17221823	07/31/2024
6.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17221830	07/31/2024
7.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17221831	08/31/2024
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

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Sr. No	NDC	Product Name	Batch No.	Expiry Date
11.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17230796	02/28/2025
12.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17230820	02/28/2025
13.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17230825	03/31/2025
14.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17230833	03/31/2025
15.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17230840	03/31/2025
16.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17231537	06/30/2025
17.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 50 count	17231540	06/30/2025
18.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17231719	06/30/2025
19.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17231737	06/30/2025
20.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 500 count	17232111	09/30/2025
21.	68001-396-03	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K – 50 count	17232164	09/30/2025

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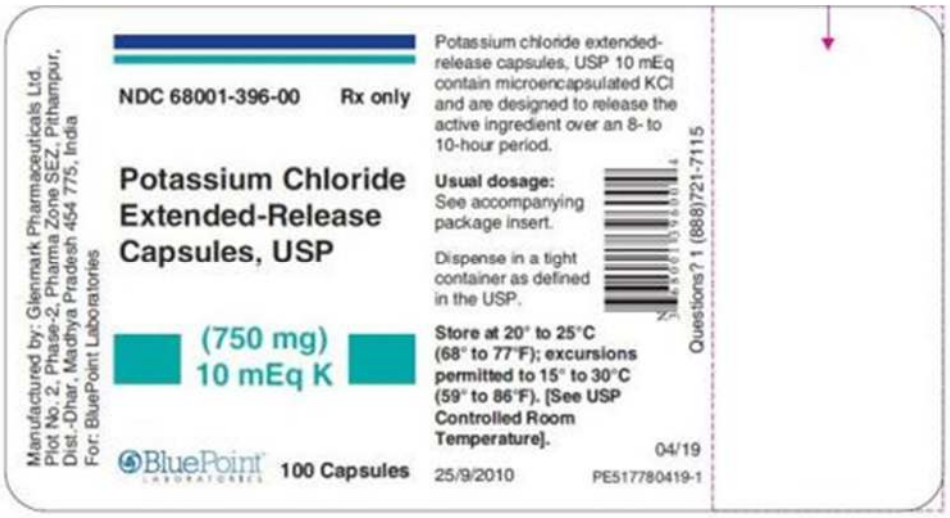
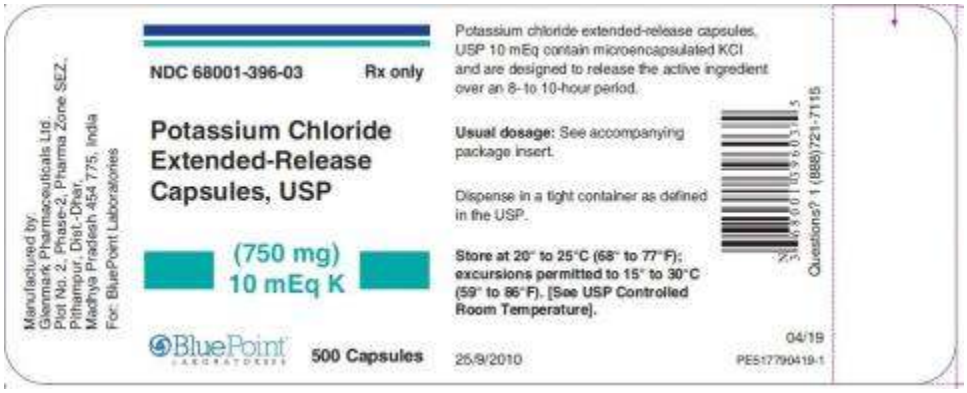
The product can be identified through the labels below:





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solution vendor, at **1-855-695-8564**, Monday - Friday, 8:00 am – 5:00 pm EST for return instructions and further information.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm 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**

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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