# Potassium Chloride ER Tablets, USP, 10 mEq (750 mg), 100 Tablets per carton (10 x 10-unit dose blisters) Class II - Retail Level Recall - CUSTOMER CARE TALK TRACK

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**Background Information:** NCQA made an update to their standard requesting communication be sent to members and prescribers affected by any recall classified as a Class II by the FDA except for wholesale level recalls. Communication is being sent to members and prescribers of NCQA delegated clients to inform them of the limited recall. **The distributor is not requiring any action on the part of consumers for these recalls.**

**This recall affects NDC # 00904-7216-61 and lot # T05224 exp. 02/2026.**

# Customer Care Talk Track:

\*\* Please ensure to disposition all recall calls to code “**1116**” \*\*

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| --- | --- | --- |
| **Q#** | **Question** | **Answer** |
| **1** | **Why did I receive a recall notice?** | Our records indicate that you may have recently received a prescription for a product affected by a limited recall from your retail pharmacy.  For more information, call the manufacturer listed on the letter or visit their website. You may also call the United States Food and Drug Administration (FDA) toll-free at 1‑888‑INFO-FDA (1‑888-463-6332) or visit [www.fda.gov](http://www.fda.gov). |
| **2** | **May I return the rest of the recalled product that I have?** | The distributor is not requiring any action on the part of consumers for these recalls. |
| **3** | **Should I stop using the recalled product?** | Please contact your prescriber with any questions or concerns about this recall or your use of the product. |

Additional Information:

Event Details

**Event ID:**

96201

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Product Type:**

Drugs

**Initial Firm Notification of Consignee or Public:**

Letter

**Status:**

Ongoing

**Distribution Pattern:**

Nationwide in the USA

**Recalling Firm:**

The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories  
341 Mason Rd  
La Vergne, TN 37086-3606  
United States

**Press Release URL(s):**

Press Release Not Issued For This Recall

**Recall Initiation Date:**

1/30/2025

**Center Classification Date:**

2/4/2025

**Date Terminated:**

N/A

**\*N/A -***Not Available*

Product Details

| **#** | **Product Description** | **Recall Number** | **Classification** | **Code Information** | **Product Quantity** | **Reason for Recall** |
| --- | --- | --- | --- | --- | --- | --- |
| 1 | Potassium Chloride Extended-Release Tablets, USP, 10 mEq (750 mg), 100 Tablets per carton (10 x 10 unit dose blisters), Rx Only, Distributed by: Aurobindo Pharma USA< INC., 279 Princeton-Hightstown Road, East Windsor, NJ 08520. Made in India. Distributed by: MAJOR PHARMACEUTICALS, Livonia, MI 48152. NDC: 0904-7216-61 | D-0221-2025 | Class II | Lot# T05224; Exp. 02/2026 | 6997 cartons | Failed Dissolution Specifications. |

Update History

**There is no history available for products in this event**

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