URGENT: DRUG RECALL

Potassium chloride Extended Release Capsules (750 mg) 10 mEq K Container Pack

(Bottle pack container 100's and 500's)

NDC for 750 mg US # 100's (68462-357-01), 500's (68462-357-05)

June 25, 2024

Dear Glenmark Customer,

This is to inform you of a voluntary recall to the Consumer level involving the following drug product: **Potassium chloride Extended Release Capsules (750 mg) 10 mEq K,** due to 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 heart beat 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.

The lot numbers and expiration dates for the product being recalled are contained in the table below:

Sr. No	NDC	Product Name	Batch No.	Expiry Date
1.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17221393	Jun-24
2.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17221403	Jun-24
3.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17221405	Jun-24
4.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17221503	Jun-24
5.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17221508	Jun-24

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Sr. No	NDC	Product Name	Batch No.	Expiry Date
6.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17221567	Jul-24
7.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17221566	Jul-24
8.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17221719	Jul-24
9.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17221731	Jul-24
10.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17221891	Aug-24
11.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17221892	Aug-24
12.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17221900	Aug-24
13.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17221992	Aug-24
14.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222022	Aug-24
15.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222056	Sep-24
16.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222043	Sep-24
17.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222068	Sep-24
18.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222079	Sep-24
19.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222099	Sep-24
20.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222103	Sep-24
21.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222114	Sep-24
22.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222119	Sep-24
23.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222188	Sep-24
24.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222199	Sep-24
25.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222209	Sep-24
26.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222200	Sep-24
27.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222265	Oct-24
28.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222269	Oct-24
29.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222527	Nov-24

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Sr. No	NDC	Product Name	Batch No.	Expiry Date
30.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222530	Nov-24
31.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222583	Nov-24
32.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17222586	Nov-24
33.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230051	Nov-24
34.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230075	Nov-24
35.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230067	Nov-24
36.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17221489	Jun-24
37.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17221504	Jun-24
38.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17221530	Jun-24
39.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17221561	Jul-24
40.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17221579	Jul-24
41.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17221568	Jul-24
42.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17221702	Jul-24
43.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17221704	Jul-24
44.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17221898	Aug-24
45.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17221993	Aug-24
46.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17222029	Aug-24
47.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17222300	Oct-24
48.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17222304	Oct-24
49.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17222278	Oct-24
50.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17222609	Oct-24
51.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17222395	Oct-24
52.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17222589	Nov-24
53.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17222605	Nov-24

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Sr. No	NDC	Product Name	Batch No.	Expiry Date
54.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17222613	Nov-24
55.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230074	Dec -24
56.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230221	Dec -24
57.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230468	Jan-25
58.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230479	Jan-25
59.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230553	Jan-25
60.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230543	Jan-25
61.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230561	Jan-25
62.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230619	Feb-25
63.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230624	Feb -25
64.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230879	Mar -25
65.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230890	Mar -25
66.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230918	Mar -25
67.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230984	Mar -25
68.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17230996	Mar-25
69.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17231002	Mar-25
70.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17231081	Mar-25
71.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17231102	Apr-25
72.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17231135	Apr-25
73.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17231329	Apr-25
74.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17231369	May-25
75.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17231513	May-25
76.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17231516	Jun-25
77.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17231713	Jun-25

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Sr. No	NDC	Product Name	Batch No.	Expiry Date
78.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17231909	Jul -25
79.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17231903	Jul -25
80.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17231943	Aug-25
81.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17232166	Sep -25
82.	68462-357-01	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 100 count	17232179	Sep -25
83.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230186	Dec-24
84.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230192	Dec-24
85.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230213	Dec-24
86.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230278	Dec-24
87.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230399	Dec-24
88.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230406	Jan-25
89.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230412	Jan-25
90.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230427	Jan-25
91.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230444	Jan-25
92.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230453	Jan-25
93.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230495	Jan-25
94.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230574	Feb-25
95.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230585	Feb-25
96.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230608	Feb-25
97.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230629	Feb - 25
98.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230883	Mar -25
99.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17230921	Mar -25
100.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17231087	Apr- 25

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Sr. No	NDC	Product Name	Batch No.	Expiry Date
101.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17231339	Apr-25
102.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17231360	May-25
103.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17231711	Jun-25
104.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17231745	Jun-25
105.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17231819	Jul-25
106.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17231820	Jul-25
107.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17231936	Jul-25
108.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17231957	Jul-25
109.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17231998	Aug-25
110.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17232012	Aug-25
111.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17232110	Sep- 25
112.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17232114	Aug-25
113.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17232119	Sep- 25
114.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEQ K - 500 count	17232343	Sep- 25

Please see details of product batches listed in above table and refer enclosed product labels for ease in identifying the product.

Glenmark will issue a credit to Glenmark customers for all returned goods associated with this recall notice consistent with our respective agreements.

***Action Required - Wholesalers and Distributors:**

1. **Stop distributing these lots immediately and segregate any affected product remaining in your inventory for return.** Glenmark Pharmaceuticals, Inc. initiated shipment of this product on 08/01/2022.

2. **Notify your retail and distributor consignees**. Include a copy of this letter to any of your direct retail or distributor consignees to whom you distributed the affected product. **Wholesalers/Distributors are to conduct a <u>sub-recall</u>** to retail / pharmacy customers, to which you have shipped the affected product, by informing them of the recall, requesting that

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they remove the affected product from sale, request your retail / pharmacy customers, to inform their consumers about the recall and return the stock to the wholesaler/distributor from which it was purchased.

Note: You must follow up with your retail / pharmacy customers who do not acknowledge the receipt of the recall notification and take appropriate actions to return the affected product.

3. After you have notified your retail and distributor consignees, complete the **enclosed Recall Return Response Form indicating that you have done so and return it immediately to Inmar Rx Solutions** at 3845 Grand Lakes Way, Grand Prairie, TX 75050.

4. After completing and returning your recall return response form, call Inmar Rx Solutions at **877-883-9273** to request a Return Authorization (RA) kit to use for return shipment and to discuss any reimbursement questions. As the RA kit will indicate, return of the product for this recall must be made **only** to Inmar Rx Solutions.

5. Once you receive the shipping label and RA kit, immediately ship any affected product to **Inmar Rx Solutions** at 3845 Grand Lakes Way, Grand Prairie, TX 75050.

6. If you do not possess any affected product in your inventory, please prepare and return a recall return response form to Inmar Rx Solutions indicating that you do not possess any of the affected product.

7. Please do not include any other product/lots in this return shipment.

Action Required - Retailer or Pharmacy:

1. **Stop dispensing these lots immediately and segregate any product remaining in your inventory for return**. Retail and hospital pharmacies that track lot number dispensed to individuals, please contact individuals who have received any of the impacted lots specified in the above table. Advise them of the recall, and recover any units of the impacted lot for return.

2. Call Inmar Rx Solutions at **877-883-9273** to request a Return Authorization (RA) kit to use for return shipment and to discuss any reimbursement questions. As the RA kit will indicate, return of the product for this recall must be made **only** to Inmar Rx Solutions.

3. Once you receive the shipping label and RA kit, immediately ship any affected product to **Inmar Rx Solutions** at 3845 Grand Lakes Way, Grand Prairie, TX 75050.

4. Please do not include any other products/lots in this return shipment.

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Action Required – Consumer/Patient/Caregiver:

1. Prior to returning the recalled medication, you should consult with your pharmacist, who can advise you about replacement or reimbursement for your medication. Since there might be a potential for adverse health consequences associated with stopping the medication, you should also consult with your healthcare provider or physician.

   Once your pharmacist has provided you with a replacement of your medication, or a healthcare provider or physician has provided you a new prescription to treat your condition, we request that you return any remaining product that is the subject of this recall to Inmar Rx Solutions.

2. Please call Inmar Rx Solutions at **877-883-9273** to request a Return Authorization (RA) kit to use for return shipment and to discuss any reimbursement questions. As the RA kit will indicate, return of the product for this recall must be made **only** to Inmar Rx Solutions.

3. Once you receive the shipping label and RA kit, immediately ship any affected product to **Inmar Rx Solutions** at 3845 Grand Lakes Way, Grand Prairie, TX 75050.

4. Please do not include any other products/lots in this return shipment.

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Please complete and return the enclosed response form preferably within 72 hours of receipt of this notification. Please either fax your response to 817-868-5362 or email to Rxrecalls@Inmar.com.

If you have any questions regarding your recall return please contact Inmar at **877-883-9273.** Inmar office hours are Monday through Friday, from 9am to 5pm EST.

This recall is being made with the knowledge of the Food and Drug Administration.

Thank you for your cooperation,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

Product Labels

Recall Return Response Form

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