

Glenmark Pharmaceuticals Inc., USA Issues Voluntary Nationwide Recall for Potassium Chloride Extended-Release Capsules, USP (750 mg) 10 mEq K Due To Failed Dissolution

Company Contact: Glenmark Drug Safety
Phone Number: 1-888-721-7115

FOR IMMEDIATE RELEASE – June 24, 2024 – Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ is voluntarily recalling 114 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 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 arrhythmias, 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.

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 68462-357-01) and 500-count (NDC 68462-357-05) 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.	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
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

Sr. No	NDC	Product Name	Batch No.	Expiry Date
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
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	17230075	Nov-24

Sr. No	NDC	Product Name	Batch No.	Expiry Date
		(750 mg) 10 mEQ K - 100 count		
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
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

Sr. No	NDC	Product Name	Batch No.	Expiry Date
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
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	17230399	Dec-24

Sr. No	NDC	Product Name	Batch No.	Expiry Date
		(750 mg) 10 mEQ K - 500 count		
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
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	17232119	Sep- 25

Sr. No	NDC	Product Name	Batch No.	Expiry Date
		(750 mg) 10 mEq K - 500 count		
114.	68462-357-05	Potassium Chloride Extended-Release Capsules USP (750 mg) 10 mEq K - 500 count	17232343	Sep- 25

The product can be identified through the labels below:

NDC 68462-357-01

**Potassium Chloride
Extended-Release
Capsules, USP**


**(750 mg)
10 mEq K**

glenmark

Rx Only 100 Capsules

Potassium chloride extended-release capsules, USP 10 mEq contain microencapsulated KCl and are designed to release the active ingredient over an 8- to 10-hour period.
Usual dosage: See accompanying package insert. Dispense in a tight container as defined in the USP.
Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature].
 Manufactured by: Glenmark Pharmaceuticals Ltd. Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Dist.-Dhar, Madhya Pradesh 454-775, India
 MP/DRUGS/25/9/2010
 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430
 03/17
 PE389420317-1

Questions? 1 (888)721-7115
www.glenmarkpharma.com/usa



NDC 68462-357-05

**Potassium Chloride
Extended-Release
Capsules, USP**

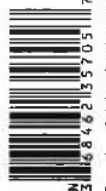
**(750 mg)
10 mEq K**

glenmark

Rx Only 500 Capsules

Potassium chloride extended-release capsules, USP 10 mEq contain microencapsulated KCl and are designed to release the active ingredient over an 8- to 10-hour period.
Usual dosage: See accompanying package insert. Dispense in a tight container as defined in the USP.
Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature].
 Manufactured by: Glenmark Pharmaceuticals Ltd. Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Dist.-Dhar, Madhya Pradesh 454-775, India
 MP/DRUGS/25/9/2010
 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430
 03/17
 PE389430317-1

Questions? 1 (888)721-7115
www.glenmarkpharma.com/usa



Glenmark 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.

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. Consumers should call Inmar Rx Solutions at 1-877-883-9273, Monday - Friday, 9:00 am – 5:00 pm EST for return instructions and for 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.