

COM-2024-040

26
June
2024

URGENT PLEASE REVIEW

Recall Notification

PharmPix Clinical Department

U.S. Food & Drug
Administration
Publication Date:

6/25/2024

Drug Information:

National Drug Code

68462-357-01

68462-357-05

Product Description:

POTASSIUM CHLORIDE EXTENDED
RELEASE 750MG CAPSULES, 100
COUNT AND 500 COUNT

Lot Number

Refer to table included in the notification

Expiration Date

Refer to table included in the notification

Company:

GLENMARK PHARMACEUTICALS INC.

QUESTIONS

Call INMAR RX SOLUTIONS, at 1-877-
883-9273 Monday – Friday, 9:00 am –
5:00 pm EST



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.

Potassium Chloride Extended-Release

It is for this reason that we are notifying you that on 06.25.2024 the US Food and Drug Administration published a drug recall for the following product(s): Potassium Chloride Extended Release 750mg Capsules.

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:

Glenmark Pharmaceuticals Inc. announced that it is voluntarily recalling 114 lots of Potassium Chloride Extended Release 750mg Capsules to the consumer level due to failed dissolution.

Risk Statement: The failed dissolution of potassium chloride extended capsules may cause high potassium levels, also known as hyperkalemia, which can result in irregular heartbeat that can lead to cardiac arrest, severe muscle weakness, and death.

Glenmark Pharmaceuticals Inc. has not received any reports of adverse events related to this recall to date.



CLINICAL PEARLS

BY PHARMPPIX

The affected Potassium Chloride Extended-Release 750mg Capsules lots include the following:

Number	NDC	Product Name	Lot 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
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

Number	NDC	Product Name	Lot No.	Expiry Date
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

Number	NDC	Product Name	Lot No.	Expiry Date
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

Number	NDC	Product Name	Lot No.	Expiry Date
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
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

Number	NDC	Product Name	Lot No.	Expiry Date
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

Number	NDC	Product Name	Lot No.	Expiry Date
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

Number	NDC	Product Name	Lot No.	Expiry Date
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(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

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- Clinical Department. 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-2024-040 June 2024



REFERENCES:

1. U.S. Food and Drug Administration. (2024). Glenmark Pharmaceuticals Inc., USA Issues Voluntary Nationwide Recall for Potassium Chloride Extended-Release Capsules, USP (750mg) 10 mEq K Due to Failed Dissolution from: [Glenmark Pharmaceuticals Inc., USA Issues Voluntary Nationwide Recall for Potassium Chloride Extended-Release Capsules, USP \(750 mg\) 10 mEq K Due to Failed Dissolution | FDA](#)
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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