State of California—Health and Human Services Agency
California Department of Public Health

Food and Drug Branch – Drug Recalls

# CALIFORNIA DRUG RECALL INFORMATION SHEET

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

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|---|---|---|---|
| **06/24/2024** | **Potassium Chloride Extended-Release Capsules USP, (750 mg) 10 mEq**<br><br>114 batches recalled<br><br>Information about the lot numbers and expiration dates for all the 114 recalled batches can be found at:<br>Table for the lot numbers and expiration dates | **Glenmark Pharmaceuticals Inc.** | Failed dissolution of potassium chloride extended release capsules may cause high potassium levels (hyperkalemia), which can result in irregular heartbeat that can lead to cardiac arrest. Especially for patients who require chronic use of potassium chloride extended-release oral capsules, and in those patients with underlying comorbidities or conditions such as hypertension, heart failure, or renal dysfunction, there is a probability of developing hyperkalemia and severe adverse events such as cardiac arrythmias, severe muscle |

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| | | | weakness, and death. |

| Recall Class | Product Identification | Distribution | Affected Dates |
|---|---|---|---|
| N/A | Bottles of 100-count capsules (NDC 68462-357-01)<br><br>Bottles of 500-count capsules (NDC 68462-357-05) capsules. | **Nationwide** | N/A |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE