American Health Packaging Issues Voluntary Nationwide Recall of Potassium Chloride Extended-Release 750 mg Capsules

Date: 06/26/2024

About this recall:
American Health Packaging on behalf of BluePoint Laboratories is voluntarily recalling 21 batches of Potassium Chloride Extended-Release (ER) capsules in the strength of 750 mg which is equivalent to 10 mEq of potassium. The recall is to the consumer level due to failed dissolution.

For lot recalls, the lot/batch information and expiration date for the recalled product can be viewed by clicking on the link to the FDA Recall Notification found on the following page.

Potassium Chloride ER Capsules are used for the treatment of patients with low potassium (hypokalemia) and are packaged in bottles of 100-count (NDC 68001-0396-00) and 500-count (NDC 68001-0396-03) capsules.

What this means to you:
If the potassium chloride ER capsules do not dissolve properly, high potassium levels (hyperkalemia) may occur which can result in irregular heartbeat that can lead to cardiac arrest. For patients who require chronic use of potassium chloride, especially in those with underlying conditions (high blood pressure, heart failure, or kidney dysfunction), the potential exists for high potassium levels to result in serious adverse events such as heart arrythmias, severe muscle weakness, or death. To date, the company has not received any reports of hyperkalemia or serious events from sources related to this recall.

Consumers that have Potassium Chloride ER Capsules with a recalled NDC and lot number should consult with their health care professional (HCP) before they stop using the product. Consumers should also contact their HCP if they have experienced any problems that may be related to taking or using this drug product. Consumers should call Sedgwick, at 1-855-695-8564, Monday to Friday, 8:00 am to 5:00 pm EST for return instructions and 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.
- Regular Mail or Fax: Download form 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 United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/american-health-packaging-behalf-bluepoint-laboratories-issues-voluntary-nationwide-recall-potassium

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.

