

Drug recall notice for potassium chloride 750 mg extended-release capsules

To assist you in the care of your patients, Humana Healthy Horizons® in Louisiana is alerting you about the recall of 114 batches of potassium chloride 750 mg extended-release capsules on June 24, 2024.¹ We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them about the recall.

The drug manufacturer, Glenmark Pharmaceuticals Inc., is voluntarily recalling these products due to the failed dissolution of the extended-release capsules. Potassium chloride extended-release capsules are used for the treatment of patients with hypokalemia, and failed dissolution can result in hyperkalemia. Hyperkalemia may be asymptomatic for some patients, but it may result in more severe and potentially life-threatening impacts, including cardiac arrythmias, severe muscle weakness and death, for some patients.

The impacted drug products list can be downloaded at the US. Food and Drug Administration (FDA) website. To date, Glenmark Pharmaceuticals has received no reports of adverse events related to this recall.

Medications included in this recall

Visit the FDA website for specific details about the recalled medication.

Information for providers:1

- We sent a letter to your Humana Healthy Horizons-covered patients with claims for potassium chloride 750 mg extended-release capsules and asked them to contact their providers if their medication is included in the recall and if they have experienced problems that could be related to using these drug products.
- Patients can report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting Program online, by phone or by fax.
 - Online: Submit the report.
 - Select "Form FDA 3500 Voluntary Reporting."
 - O Phone or fax: Download the form.
 - Complete and submit "Form FDA 3500 Voluntary Reporting" by phone at 1-800-FDA-1088 (332-1088) or by fax to 1-800-FDA-0178 (332-0178).

Note: A reporting form also can be requested by calling 1-800-FDA-1088 (332-1088).

Humana Healthy Horizons in Louisiana is a Medicaid Product of Humana Health Benefit Plan of Louisiana, Inc.

Reference

1. "Glenmark Pharmaceuticals Inc., USA Issues Voluntary Nationwide Recall for Potassium Chloride Extended-Release Capsules, USP (750 mg) 10 mEq K Due to Failed Dissolution," U.S. Food and Drug Administration, last accessed July 30, 2024, www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/glenmark-pharmaceuticals-inc-usa-issues-voluntary-nationwide-recall-potassium-chloride-extended.