ICU Medical Issues Nationwide Recall of POTASSIUM CHLORIDE INJECTION, 20 mEq and POTASSIUM CHLORIDE INJECTION, 10 mEq Due to Mislabeling

February 13, 2025

February 13, 2025 LAKE FOREST, Illinois – ICU Medical, Inc. is voluntarily recalling one lot each of POTASSIUM CHLORIDE Inj. bags with overwrap labels 10mEq, packaged in cases of POTASSIUM CHLORIDE Inj. 20 mEq, to the user level. ICU Medical has received a customer complaint which states that bags of POTASSIUM CHLORIDE Inj. **20 mEq** have incorrect overwrap labels which state POTASSIUM CHLORIDE Inj. **10 mEq**.

ICU Medical has identified a potential for some of the product overwraps in one lot being mislabeled as 10 mEq (instead of 20 mEq that is contained in the I.V. Bag) of POTASSIUM CHLORIDE due to a manufacturing issue. The 20 mEq, correctly printed on the labeling affixed to the bag, is not visible or not easily visible without manipulation when the 10 mEq overwrap is in place.

Risk Statement: If the Health Care provider mistakenly calculates the patient dose using 10 mEq, the patient will receive an overdose of potassium chloride. Severe hyperkalemia after large intravenous overdoses causes neuromuscular dysfunction including muscle weakness, ascending paralysis, listlessness, vertigo, mental confusion, hypotension, cardiac dysrhythmias, or death from cardiac arrest. Premature infants, patients on chronic parenteral nutrition, patients who have a history of cardiac arrythmias, patients with chronic renal insufficiency, patients who have acute renal failure, patients on potassium-sparing diuretics—all are at risk for adverse and potentially fatal outcomes. ICU Medical has not received reports of adverse events associated with this issue to date.

Potassium Chloride Injection 20 mEq and 10 mEq, is indicated in the treatment of potassium deficiency states, when oral replacement is not feasible and is packaged in 100 mL bags. The mislabeled POTASSIUM CHLORIDE Inj. 20 mEq, 100 mL bags contain incorrect overwrap labels with the following information: NDC 0990-7074-26, 200 mEq/L POTASSIUM CHLORIDE Inj. 10 mEq. The lot 1023172 and Exp. Date 31 January 2026 is found on the primary container (see picture below). These mislabeled bags are packaged in cases labeled: NDC 0990- 7075-26, CASE PACK 1x24 – 100ML 20MEQ POTASSIUM CHLORIDE INJECTION LOT NO. 1023172, EXP DATE 2026-01.

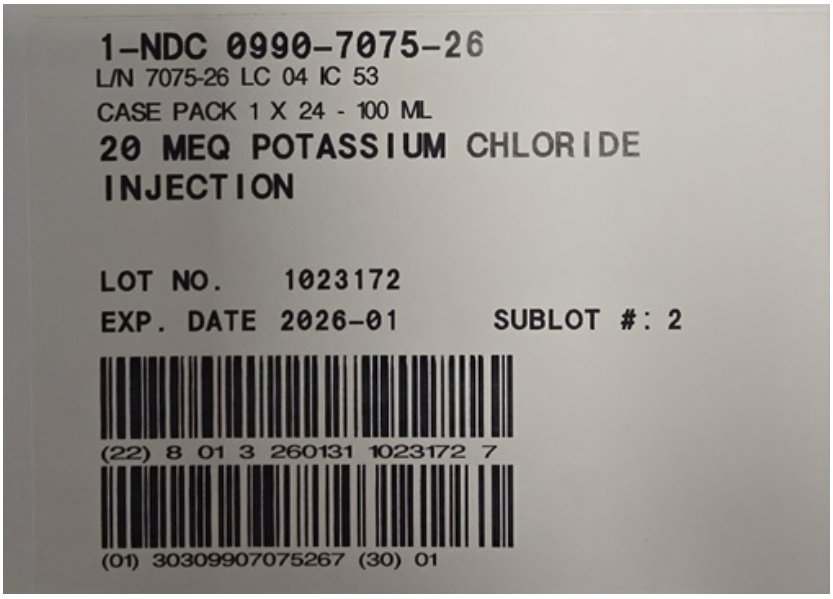
DESCRIPTION OF MISLABELED BAGS BEING RECALLED:

NDC Number	Barcode Number	Product Overwrap Description	Product Primary Bag Description	Lot Number	Expiration Date	Configuration
0990-7074-26	(01)00309907074269	POTASSIUM CHLORIDE Inj. 10 mEq	POTASSIUM CHLORIDE Inj. 20 mEq	1023172	31 January 2026	100 mL Flexible Container
0990-7075-26	(01)00309907075266	POTASSIUM CHLORIDE Inj. 20 mEq	POTASSIUM CHLORIDE Inj. 20 mEq	1023172	31 January 2026	100 mL Flexible Container

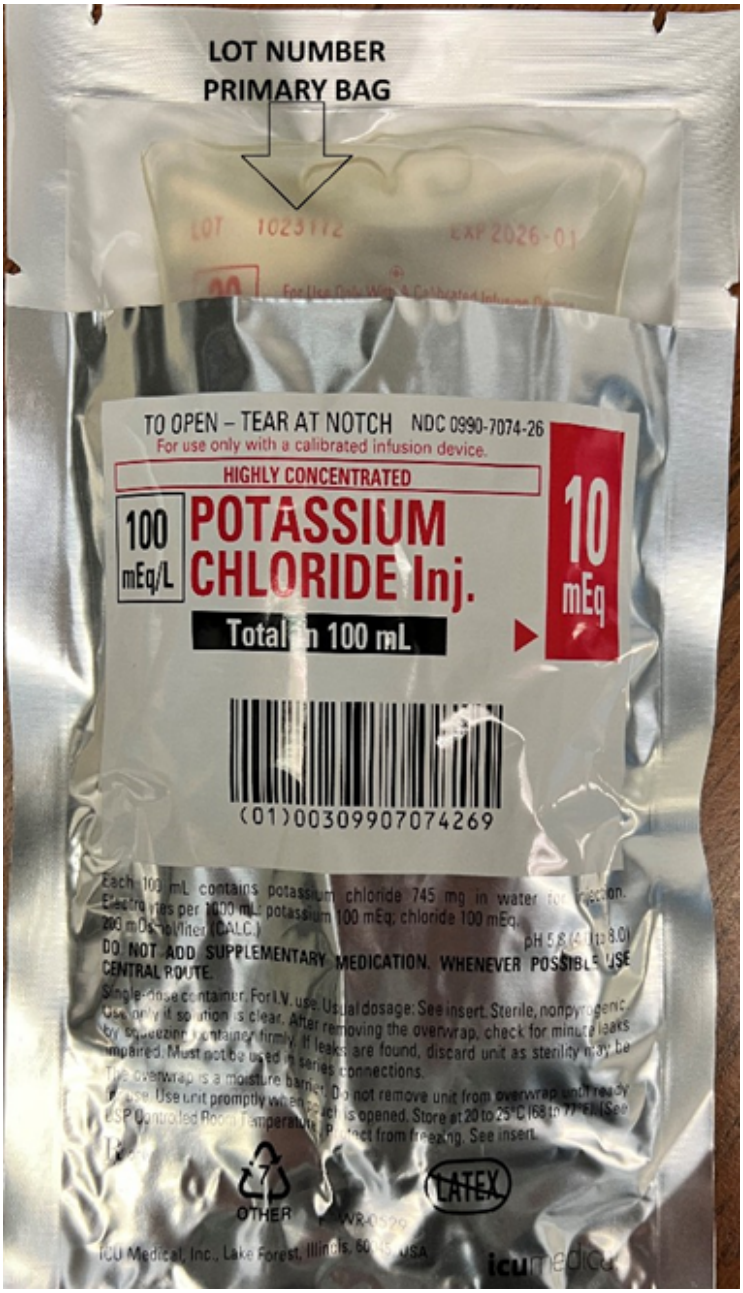
DESCRIPTION OF CASES BEING RECALLED:

NDC Number	Barcode Number	Lot Number	Expiration Date	Configuration
0990-7075-26	(01)30309907075267	1023172	31 January 2026	1 x 24 – 100 mL

Example Case Label:



Mislabeled OVERWRAP: Overwrap and Product Image:



INCORRECT OVERWRAP

CORRECT OVERWRAP

ICU Medical is notifying its customers, including distributors, of this recall by letter, and is arranging for the return of all recalled product. All Health Care professionals that have product that is being recalled should stop use/further distribution, as applicable, and return to place of purchase.

Consumers with questions regarding this recall can contact ICU Medical by phone number or e-mail address as indicated in the table below. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

For further inquiries, please contact ICU Medical using the information provided below.

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-844-654-7780 or ProductComplaintsPP@icumed.com M-F 8-5 CST	To report product complaints
Drug Safety	1-844-654-7780 or DrugSafety@icumed.com M-F 8-5 CST	To report adverse events for IV Solutions & Drugs
Medical Information	1-800-241-4002, option 6 or medinfo_us@icumed.com M-F 8-5 CST	Medical inquiries
Customer Care	1-877-946-7747, option 1 M-F 7-6 CST	Product Replacement Options

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:** fda.gov/medwatch/report.htm
- **Regular Mail** or **Fax:** Download form 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.

Contact:

Consumers

ICU Medical, Inc. 1-844-654-7780

Media Contact: Harrison Richards ICU Medical, Inc. 949-366-4261

Harrison.Richards@icumed.com