600 N. Field Drive
Lake Forest, IL 60045
www.icumed.com

URGENT DRUG RECALL

POTASSIUM CHLORIDE INJECTION, MISLABELED OVERWRAP LABELLED AS 10 mEq PRODUCT LABEL STATES 20mEq AND CONTAINS 20 mEq POTASSIUM CHLORIDE INJECTION

13 February 2025

Dear Valued Customers:
Director of Risk Management
Director of Materials Management
Director of Pharmacy

ICU Medical, Inc. is issuing a voluntary recall to the user level, for a MISLABELLED lot of POTASSIUM CHLORIDE Inj. 20 mEq, NDC 0990-7075-26. The **OVERWRAP** label of lot 1023172, Expiration Date: 01-31-2026, incorrectly identifies the product as POTASSIUM CHLORIDE Inj. 10 mEq with NDC 0990-7074-26. This notification details the issue and the required steps for you to perform.

Issue:
ICU Medical has identified a potential for some of the product overwraps in one lot being mislabeled as 10 mEq (instead of 20 mEq) of POTASSIUM CHLORIDE due to a manufacturing issue. The dosage is correctly printed on the labeling affixed to the product bag which is not visible when the 10 mEq OVERWRAP is in place.

Potential Risk:
If the incorrect dosage on 10 mEq overwrap is used instead of the correct 20mEq dosage printed on the product, an overdose of potassium chloride is possible. Overdose of potassium chloride can lead to hyperkalemia. ICU Medical has not received reports of adverse events associated with this issue to date.

Affected Product:
The affected product lot was manufactured on 24 September 2024 and distributed in the United States between 15 November 2024 through 17 December 2024. The affected product lot is:

NDC Number	List Number	Product Description	Lot Number	Expiration Date	Configuration	Label Example – Product Container
0990-7075-26	070750453	POTASSIUM CHLORIDE Inj. 20 mEq	1023172	31 January 2026	100 mL Flexible Container	

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Overwrap Label Examples:

INCORRECT OVERWRAP

TO OPEN – TEAR AT NOTCH NDC 0990-7074-26
For use only with a calibrated infusion device.
HIGHLY CONCENTRATED
100 mEq/L POTASSIUM CHLORIDE Inj.
Total in 100 mL
10 mEq

(01)00309907074269

Each 100 mL contains potassium chloride 745 mg in water for injection. Electrolytes per 1000 mL: potassium 100 mEq; chloride 100 mEq.
200 mOsmol/liter (CALC.) pH 5.8 (4.0 to 8.0)
DO NOT ADD SUPPLEMENTARY MEDICATION. WHENEVER POSSIBLE USE CENTRAL ROUTE.
Single-dose container. For I.V. use. Usual dosage: See insert. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections.
The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See insert.
℞ only
7 OTHER
LATEX
F WR-0529
ICU Medical, Inc., Lake Forest, Illinois, 60045, USA
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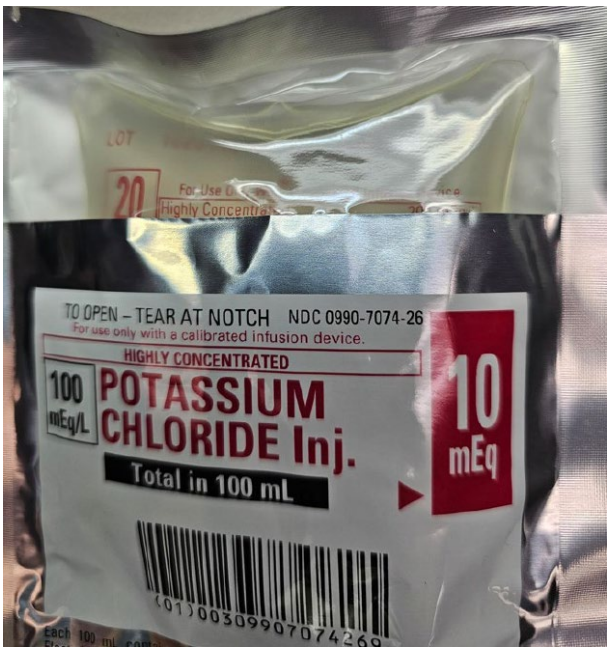
CORRECT OVERWRAP

TO OPEN – TEAR AT NOTCH NDC 0990-7075-26
For use only with a calibrated infusion device.
HIGHLY CONCENTRATED
20 mEq POTASSIUM CHLORIDE Inj. 200 mEq/L
Total in 100 mL

(01)00309907075266

Each 100 mL contains potassium chloride 1490 mg in water for injection. Electrolytes per 1000 mL: potassium 200 mEq; chloride 200 mEq.
400 mOsmol/liter (CALC.) pH 5.8 (4.0 to 8.0)
DO NOT ADD SUPPLEMENTARY MEDICATION. WHENEVER POSSIBLE USE CENTRAL ROUTE.
Single-dose container. For I.V. use. Usual dosage: See insert. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections.
The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See insert.
℞ only
7 OTHER
LATEX
F WR-0531
ICU Medical, Inc., Lake Forest, Illinois, 60045, USA
icumedical

Overwrap and Product Image Mislabeled Example:



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Required Actions:

1. Inform potential users of the product in your organization of this notification and quarantine effected product.

2. Complete the attached response form. Return the completed response form to the fax number or e-mail address on the form, even if you do not have the affected product.

3. Return affected product using the return label provided with this letter. Contact Sedgwick at 1-888-566-2363 (M-F, 8am-5pm ET) if you have not received a return label or require additional labels for returning the affected product. The return labels are for single use only. Please do not reproduce. Please visit http://expertezlabel.com to request additional labels for returning affected product. To ensure proper and timely credit, follow the instructions on the response form for returning product. Upon receipt of the completed response form and return of the affected product, ICU Medical, Inc. will credit you for any product returned. You will only receive credit for product that you return. NOTE: Credits for product purchased through distributor will be credited by the distributor.

4. If you have distributed the product further, immediately notify your accounts that received the product identified above of this notification and ask them to contact Sedgwick at 1-888-566-2363 (M-F, 8am-5pm ET) to obtain a response form.

To return affected product or if you require assistance, please contact Sedgwick at 1-888-566-2363 (M-F, 8am to 5pm ET) to obtain a return label.

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	To report product complaints
Drug Safety	1-844-654-7780 or DrugSafety@icumed.com	To report adverse events for IV Solutions & Drugs
Medical Information	1-800-241-4002, option 6 or medinfo_us@icumed.com	Medical inquiries
Customer Care	1-877-946-7747, option 1	Product Replacement Options

The U.S. Food and Drug Administration (FDA) has been notified of this action.

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

ICU Medical is committed to patient safety, providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

Stuart Green
Digitally signed by Stuart Green
Date: 2025.02.11 11:10:36 -06'00'

Stuart Green
Senior Director, Quality

Jesús Cabrera, MD PhD
Chief Medical Officer, Medical Affairs

Enclosures:

- Response Form