Otsuka ICU Medical LLC

3900 Howard Lane
Austin, TX 78728
www.otsukaicumed.com

URGENT DRUG RECALL

0.9% SODIUM CHLORIDE Injection, USP, 100 mL

11 September 2026

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

Otsuka ICU Medical LLC is issuing a voluntary recall for one lot of 0.9% SODIUM CHLORIDE Injection, USP, 100mL single pack due to potential mix-up with 10 mEq Highly Concentrated POTASSIUM CHLORIDE Injection 100 ml bag being found inside an overwrap of 0.9% SODIUM CHLORIDE Injection, USP 100 mL. This recall notification is being sent to user level customers and details the issue and the required steps for you to perform.

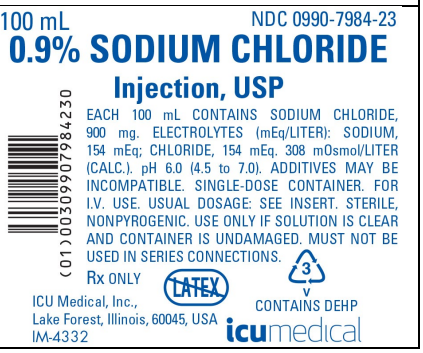
Issue:
This issue pertains to one lot of 0.9% SODIUM CHLORIDE Injection, USP (NDC: 0990-7984-23 Lot 1042188). This lot may potentially contain the overwrap with labeling indicating it to be 0.9% SODIUM CHLORIDE Injection, USP (NDC: 0990-7984-23) but the actual product within the overwrap may be POTASSIUM CHLORIDE Inj. 10 mEq, (NDC 0990-7074-26) Lot 1035181. An image of the overwrap and the mixed-up product is provided below. Please note that the incorrect product being overwrapped with a Sodium Chloride overwrap contains its own label and clearly indicates it to be POTASSIUM CHLORIDE Inj. 10 mEq.

The issue has been identified through a customer complaint.

Potential Risk:
If the Potassium Chloride is utilized instead of the intended 0.9% Sodium Chloride dosage printed on the product overwrap, an incorrect dose and/or overdose of potassium chloride is possible. Overdose of potassium chloride can lead to hyperkalemia. To date, Otsuka ICU Medical LLC has received no reports of adverse events related to this issue.

Affected Product:
The affected product lot was manufactured on 13 November 2025 and distributed in the United States between 30 December 2025 and 22 June 2026. The affected product information is provided in Table 1 below:

Table 1: Affected Product

NDC Number	List Number	Product Description	Lot Number	Expiration Date	Configuration	Label Example
0990-7984-23	07984-23	0.9% SODIUM CHLORIDE Injection, USP	1042188	31 October 2027	100 mL in flexible container	

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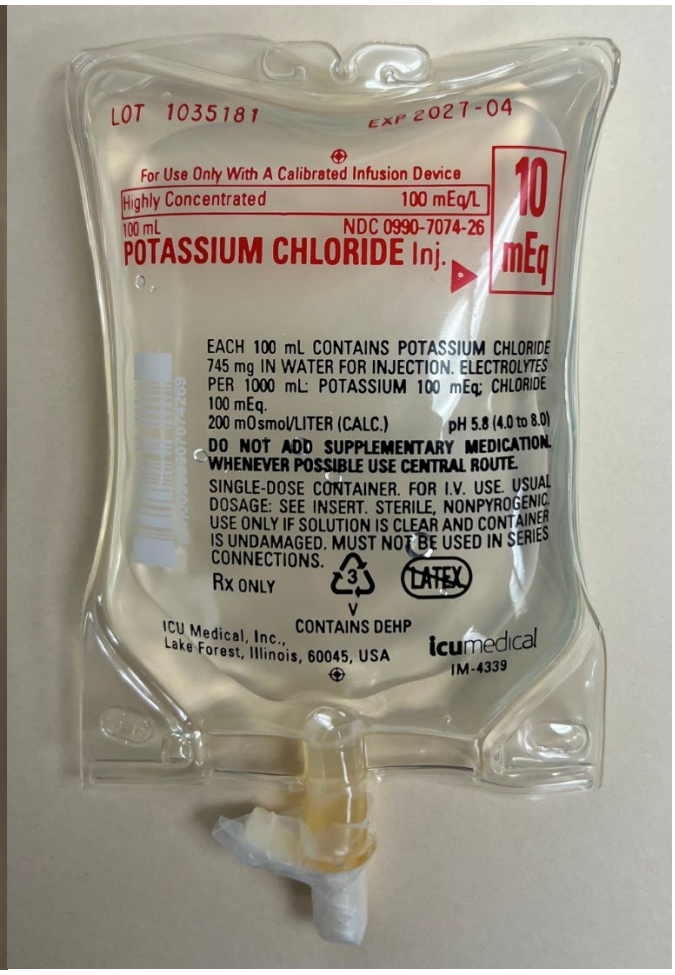
CORRECT OVERWRAP

INCORRECT IV BAG IN OVERWRAP



Required Actions for Users:

1. Inform potential users of the affected product in your organization of this notification. Check all inventory locations within your institution for the affected product in Table 1, quarantine and discontinue use.

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

3. Upon receipt of the completed response form, ICU Medical Customer Service will contact you to coordinate a return label and instructions for product return. Upon receipt of the completed response form and return of the eligible product within 90 days, ICU Medical will credit you for any returned eligible product. 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 return the completed response form(s) to marketaction@mailac.custhelp.com.

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

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-(866)-216-8806 or globalcomplaints@icumed.com	Reporting product complaints
Drug Safety	1-844-654-7780 or DrugSafety@icumed.com	Reporting adverse events for IV Solutions & Drugs
Medical Information	1-800-241-4002, option 6 or medinfo_us@icumed.com	Medical inquiries
Customer Care	1-(800)-258-5361 or customerservice@icumed.com	Product credit Return instructions
Field Action Processing	marketaction@mailac.custhelp.com	Questions about this action and response forms

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 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 at 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

Otsuka ICU Medical LLC 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: 2026.09.11 15:47:19 -05'00'

Stuart Green
Senior Director, Quality

Enclosures:

- Response Form