November 18, 2025

PROVIDER ALERT

To: Health Plan of San Joaquin/Mountain Valley Health Plan ("Health Plan") Practitioners, Facilities, and Hospitals
From: Health Plan
Type: Informational/Educational
Subject: **FDA Drug Recall Alert – Potassium Chloride Injection, 20 mEq**
Business: Medi-Cal Managed Care

On November 03, 2025, the Food and Drug Administration (FDA) released a recall announcement on **Potassium Chloride Injection, 20 mEq**.

This is for informational purposes only. You may or may not have administered the medication. Please disregard if you have not been affected by this recall.

For the complete details regarding this recall announcement, please visit the following web link: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/otsuka-icu-medical-llc-issues-voluntary-nationwide-recall-20-meq-potassium-chloride-injection-due?utm_medium=email&utm_source=govdelivery#recall-announcement

Otsuka ICU Medical LLC Issues Voluntary Nationwide Recall of 20 mEq Potassium Chloride Injection Due To Overwrap Mislabeled As 10 mEq Potassium Chloride Injection

Summary

Company Announcement Date: October 31, 2025
FDA Publish Date: November 03, 2025
Product Type: Drugs
Reason for Announcement: Potential for Potassium chloride overdose: 20 mEq Potassium Chloride Injection is Mislabeled As 10 mEq Potassium Chloride Injection
Company Name: Otsuka ICU Medical LLC
Brand Name: ICU Medical
Product Description: 20 mEq Potassium Chloride Injection

Company Announcement

FOR IMMEDIATE RELEASE – October 31, 2025 AUSTIN, TX – Otsuka ICU Medical LLC is issuing a voluntary recall to the user level, for a MISLABELLED lot of POTASSIUM CHLORIDE Inj. 20 mEq, NDC 0990-7077-14. The OVERWRAP label of lot 1030613, Expiration Date: 09-30-2026 may incorrectly identify the product as POTASSIUM CHLORIDE Inj. 10 mEq with NDC 0990-7074-26. Otsuka ICU Medical LLC has identified this discrepancy 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. This notification details the issue and the required steps for you to perform.

If the incorrect dosage on the 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. Hazards of 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. Otsuka ICU Medical LLC has not received reports of adverse events associated with this issue to date.

INDICATIONS AND USAGE:

Potassium Chloride Injection 20 mEq and 10 mEq, is indicated in the treatment of potassium deficiency states, when oral replacement is not feasible.
THIS HIGHLY CONCENTRATED, READY-TO-USE POTASSIUM CHLORIDE INJECTION IS INTENDED FOR THE MAINTENANCE OF SERUM K+ LEVELS AND FOR POTASSIUM SUPPLEMENTATION IN FLUID RESTRICTED PATIENTS WHO CANNOT ACCOMMODATE ADDITIONAL VOLUMES OF FLUID ASSOCIATED WITH POTASSIUM SOLUTIONS OF LOWER CONCENTRATION. TO AVOID POTASSIUM INTOXICATION, DO NOT INFUSE THESE SOLUTIONS RAPIDLY.
When using these products, these patients should be on continuous cardiac monitoring and frequent testing for serum potassium concentration and acid-base balance.

The affected product lot was manufactured on 15 April 2025 and distributed in the United States between 23 May 2025 through 26 August 2025. The affected product lot (Located on the top left of the product bag or the case label is:

NDC Number	List Number	Product Description	Lot Number	Expiration Date	Configuration
0990-7077-14	070770452	POTASSIUM CHLORIDE Inj. 20 mEq	1030613	30 September 2026	50mL in Flexible Container
0990-7074-26	070740452	POTASSIUM CHLORIDE Inj. 10 mEq	N/A	N/A	100mL in Flexible Container

DESCRIPTION OF CASES BEING RECALLED:

NDC Number	Barcode Number	Lot Number	Expiration Date	Configuration
0990-7077-14	(01)20309907077141	1030613	30 September 2026	24/case

Overwrap Label Examples: See below

Overwrap and Product Image Mislabeled Example: See below

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

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 Otsuka ICU Medical LLC using the information provided below.

Otsuka ICU Medical LLC Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com 1-(866)-216-8806	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	customerservice@icumed.com 1-(800)-258-5361	Product Credit
Field Action Processing	marketaction@mailac.custhelp.com	Questions about this action and response forms

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

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

Company Contact Information

Consumers:

(844) 654-7780

Media:

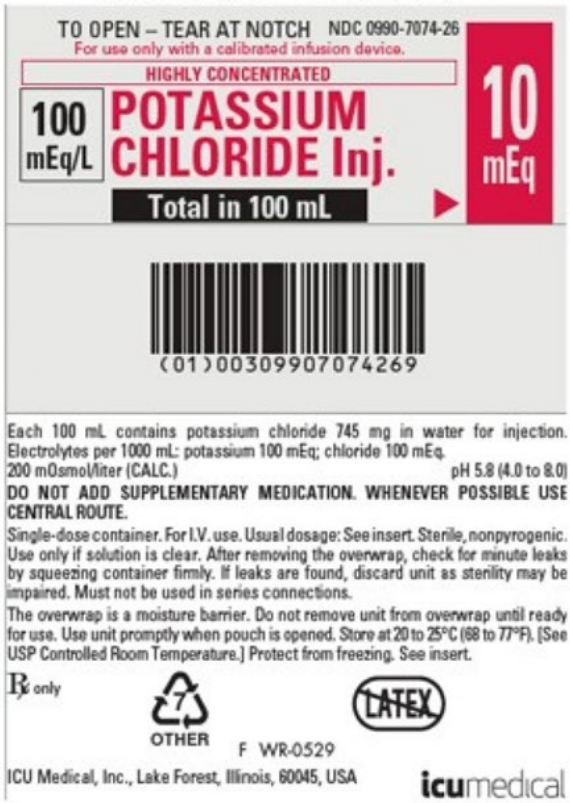
Harrison Richards

(949) 366-4261

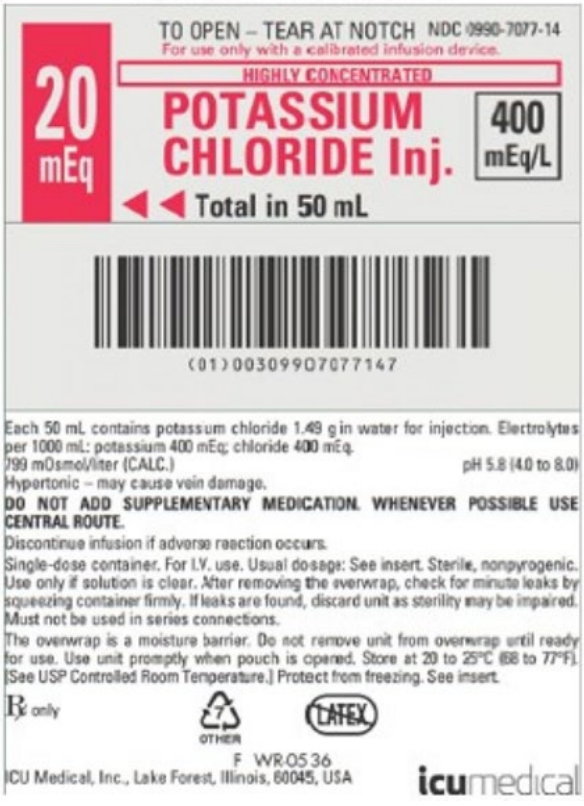
Harrison.Richards@icumed.com

Product Photos

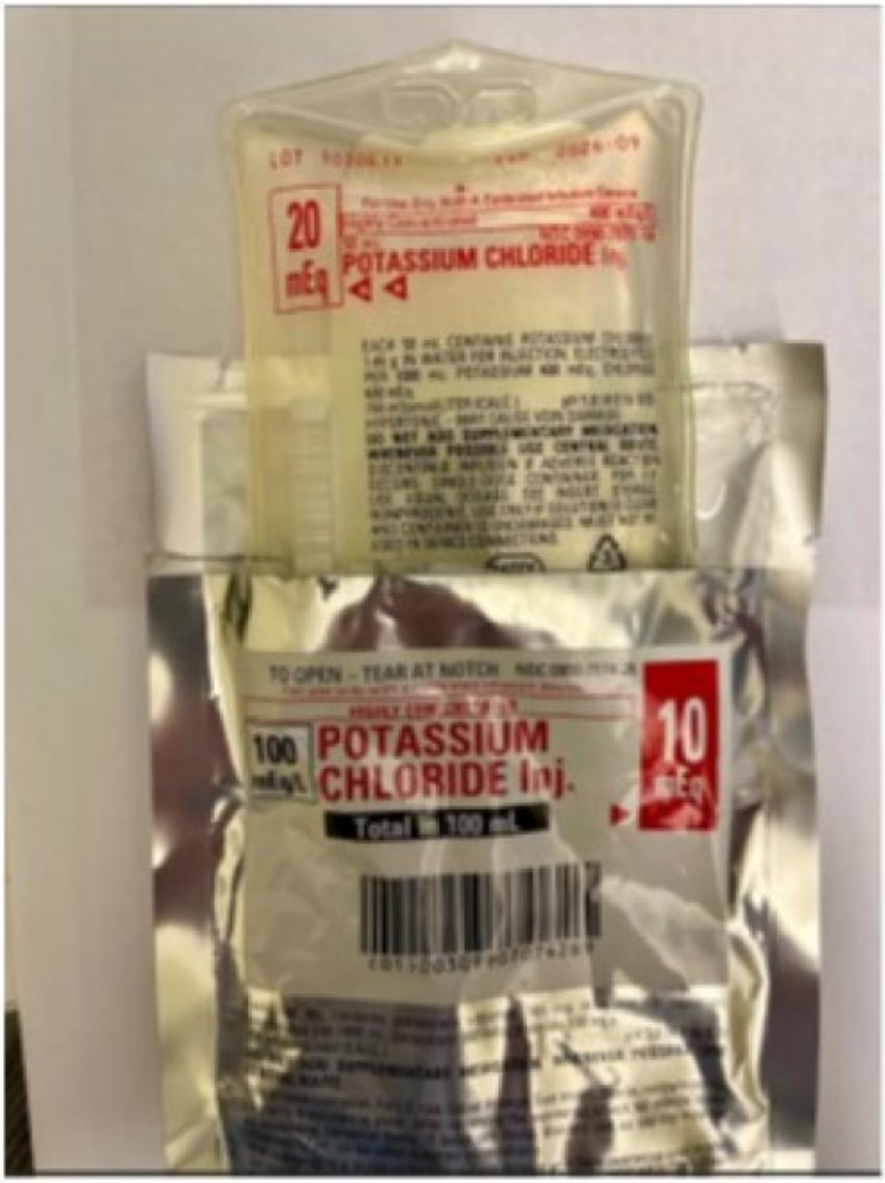
INCORRECT OVERWRAP



CORRECT OVERWRAP



Overwrap and Product Image Mislabeled Example:



If you have any further questions, please contact your Provider Services Representative, or call our Customer Service Department at 1-888-936-PLAN (7526). You may also visit https://www.hpsj.com/alerts/ for online access to the documents shared. The most recent information about Health Plan and our services is always available on our website WWW.HPSJ-MVHP.ORG.