

October 01, 2026



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 – 0.9% Sodium Chloride Injection, USP**
Business: Medi-Cal Managed Care and Medicare Dual Special Needs Plan
(D-SNP)

On September 21, 2026, the Food and Drug Administration (FDA) released a recall announcement on **0.9% Sodium Chloride Injection, USP**.

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-09-sodium-chloride-injection-usp-due?utm_medium=email&utm_source=govdelivery

Otsuka ICU Medical LLC Issues Voluntary Nationwide Recall of 0.9% Sodium Chloride Injection, USP Due To a Product Mix-up with 10 mEq Potassium Chloride Injection

Company Announcement

September 17, 2026 AUSTIN, TX – Otsuka ICU Medical LLC is issuing a voluntary recall for one lot of 0.9% SODIUM CHLORIDE Injection, USP, 100mL single pack to the user level due to a potential mix-up. The affected lot of 0.9% SODIUM CHLORIDE Injection, USP (NDC: 0990-7984-23 Lot 1042188) 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. The issue has been identified through a customer complaint where a 10 mEq Highly Concentrated POTASSIUM CHLORIDE Injection 100 mL bag was found inside an overwrap of 0.9% SODIUM CHLORIDE Injection, USP 100 mL.

Affected Products

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

Product	NDC	Lot	Expiration Date
0.9% SODIUM CHLORIDE Injection, USP	0990-7984-23	1042188	31 October 2027

Description Of Cases Being Recalled:

NDC Number	Barcode Number GTIN	Lot	Expiration Date	Configuration
0990-7984-23	(01)30309907984231	1042188	31 October 2027	100 mL in flexible container

What to Do

Otsuka ICU Medical LLC is notifying its customers, including distributors, of this recall by letter and is requesting the return of all recalled products. All customers, including distributors, should check inventory locations within their institution for the affected product in Table 1, quarantine, and discontinue use.

Upon receipt of the completed response form, ICU Medical Customer Service will contact customers to coordinate a return label and instructions for product return.

Contact Information

Consumers: (844) 654-7780	Media: Harrison Richards (949) 366-4261 Harrison.Richards@icumed.com
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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.