

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Otsuka ICU Medical LLC is issuing a 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 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.

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.

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 below.

PRODUCT: 0.9% SODIUM CHLORIDE Injection, USP, 100 mL in flexible container

NDC NUMBER: 0990-7984-23

LOT NUMBER: 1042188

EXPIRATION DATE: 10/31/2027