

*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 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, incorrectly identifies the product as POTASSIUM CHLORIDE Inj. 10 mEq with NDC 0990-7074-26.

Otsuka ICU Medical LLC 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.

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. Otsuka ICU Medical LLC has not received reports of adverse events associated with this issue to date.

The affected product lot was manufactured on 15 April 2025 and distributed in the United States between May 23, 2025 through August 26, 2025.

PRODUCT: POTASSIUM CHLORIDE Inj. 20 mEq

NDC NUMBER: 0990-7077-14

LOT NUMBER: 1030613

EXPIRATION DATE: 9/30/2026