COMMUNICATION

COM-2025-080

10 NOVEMBER 2025

URGENT PLEASE REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

11/03/2025

Drug Information:

Product Description

20 mEq Potassium Chloride Injection

Lot Number

1030613

Expiration Date

9/30/2026

Company:

Otsuka ICU Medical LLC

QUESTIONS

Contact Sedgwick at 1-888-566-2363 (M-F, 8am to 5pm ET)

Recall of 20 mEq Potassium Chloride Injection

It is for this reason that we are notifying you that on 11.03.2025, the U.S. Food and Drug Administration (FDA) published a drug recall for the following product(s): 20 mEq Potassium Chloride Injection.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Reason for Recall

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.

Risk Statement

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. An overdose of potassium chloride can lead to hyperkalemia. 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.

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

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- ext.219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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REFERENCES:

1. U.S. Food and Drug Administration. (2025). *Otsuka ICU Medical LLC Issues Voluntary Nationwide Recall of 20 mEq Potassium Chloride Injection Due To Overwrap Mislabeled As 10 mEq Potassium Chloride Injection*. Retrieved November 03, 2025 from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/otsuka-icu-medical-llc-issues-voluntary-nationwide-recall-20-meq-potassium-chloride-injection-due
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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2 Street 1, Suite 500
Guaynabo, PR 00968

Tel. 787.522.5252
Fax 866.912.2830

www.pharmpix.com
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