COMMUNICATION

COM-2025-048

18 JULY 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:

07/15/2025

Drug Information

National Drug Code

Refer to the table included in the notification

Product Description

Cefazolin for Injection, USP, 1 gm vial

Lot Number

Refer to the table included in the notification

Expiration Date

11/2027

Company:

Sandoz Inc.

QUESTIONS

Call Sedgwick at (844) 265-7409 between the hours of 8:00 AM to 5:00 PM Monday - Friday (EST).

Cefazolin for Injection, USP 1 gram per vial

It is for this reason that we are notifying you that on 07.15.2025 the U.S. Food and Drug Administration (FDA) published a drug recall for the following product(s): Cefazolin for Injection, USP, 1 gm vial.

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

Sandoz is initiating a voluntary recall of an additional lot of *Cefazolin for Injection, USP, 1 gram per vial*. This additional lot is being recalled due to a customer complaint indicating that four (4) *Penicillin G Potassium for Injection, USP, 20 million Units* labeled vials were incorrectly included in a carton (25 vials per carton) of *Cefazolin for Injection, USP, 1 gram per vial*.

Risk Statement:

There is a reasonable probability that the inadvertent administration of penicillin G potassium injection, instead of intended cefazolin injection, may pose serious and potentially life-threatening adverse health consequences, including lack of efficacy leading to less than optimal treatment of severe infections, antibiotic resistance, adverse reactions, severe allergic reactions, drug interactions, cardiac arrhythmias resulting from high potassium especially in patients with kidney impairment, and delayed recovery.

To date, Sandoz has not received any reports of adverse events or injuries related to this recall. Sandoz has received a complaint of inadvertent administration of the incorrect product to a patient.

Description of products recalled and products mispackaging:

Product Name	Vial NDC	Carton NDC	Lot Number	Expiration date	Manufacturer	Distributor
Cefazolin for Injection, USP (25 by 1g vials)	0781-3451-70	0781-3451-96	PG4360	2027-NOV	Sandoz GmbH	Sandoz Inc
Penicillin G Potassium for Injection, USP	0781-6136-94	N/A	PG4360	2027-NOV	Sandoz GmbH	Sandoz Inc
Cefazolin for Injection, USP (25 by 1g vials)	0781-3451-70	0781-3451-96	PG4362	2027-NOV	Sandoz GmbH	Sandoz Inc
Penicillin G Potassium for Injection, USP	0781-6136-94	N/A	PG4362	2027-NOV	Sandoz GmbH	Sandoz Inc

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/.

PharmPix Drug Recall Communication Number COM-2025-048 July 2025

pharmpix
POWERED BY ONEARK

REFERENCES:

1. U.S. Food and Drug Administration. (2025). UPDATE - Sandoz Inc. Issues Voluntary Nationwide Recall Expansion of One Additional Lot of Cefazolin for Injection Due to Product Mislabeling. U.S. Food and Drug Administration. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/update-sandoz-inc-issues-voluntary-nationwide-recall-expansion-one-additional-lot-cefazolin.
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

urac ACCREDITED Pharmacy Benefit Management