

July 09, 2025



To: Health Plan Practitioners, Facilities, and Hospitals
From: Health Plan of San Joaquin/Mountain Valley Health Plan ("Health Plan")
Subject: **FDA Drug Recall Alert - Cefazolin for Injection, USP, 1 gm vial**
Products: Medi-Cal Managed Care

On June 27, 2025, the Food and Drug Administration (FDA) released a recall announcement on **Cefazolin for Injection, USP, 1 gm vial**.

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: [ASandoz Inc. Issues Voluntary Nationwide Recall of One Lot of Cefazolin for Injection Due to Product Mispackaging | FDA](#)

Sandoz Inc. Issues Voluntary Nationwide Recall of One Lot of Cefazolin for Injection Due to Product Mispackaging

Company Announcement

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

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 (e.g., *anaphylaxis*), 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.

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 is used for the treatment of infections caused by certain bacteria in many different parts of the body including the treatment of pneumonia. Cefazolin for Injection USP can also be used to prevent infections, before and after surgery. Antibacterial drugs like Cefazolin for Injection USP treat only bacterial infections. They do not treat viral infections. Cefazolin for Injection USP is indicated for adult, elderly, pediatric patients, including newborn term infants.

Penicillin G Potassium for Injection is indicated in the treatment of certain serious infections including septicemia, skin and wound infections. It is also approved for the treatment of diphtheria, community-acquired pneumonia, peritonitis, meningitis/brain abscesses, osteomyelitis, infections of the genital tract, anthrax, tetanus, gas gangrene, listeriosis, pasteurellosis, rat bite fever, fusospirochetes, actinomycosis, complications in gonorrhea and syphilis and Lyme. To reduce the development of drug-resistant bacteria and maintain effectiveness of Penicillin G Potassium for Injection, USP and other antibacterial drugs, Penicillin G Potassium for Injection, USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Penicillin G Potassium for Injection is indicated for use in adults, adolescents, children, pediatric, newborn infants and preterm infants.

Although both Cefazolin and Penicillin G Potassium belong to the beta-lactam group of antibiotics, they are indicated for different types of infections, and the spectrum of susceptible organisms also differs. Additionally, while the patient populations overlap, each medicine has specific on-label distinct groups, and the dosing regimens may differ, as well.

Sandoz is notifying its customers by letter and is arranging for return of the recalled product. The product being recalled was shipped to select wholesalers for further distribution nationwide. Healthcare providers and customers who have this product should immediately stop use of this lot only and contact Sedgwick, the Sandoz Reverse Distributor, directly by phone at (844) 491-7872 or by email at Sandoz6004@sedgwick.com.

For questions about the recall process, please call Sedgwick at (844) 491-7872 between the hours of 8:00 AM to 5:00 PM Monday - Friday (EST).

Please report any adverse reactions by calling Sandoz at (800) 525-8747. Customer service agents are available from 8:30 AM to 5:00 PM (EST), Monday-Friday, except on national holidays.

Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm¹
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm² 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information:

Consumers:

Sedgwick
844-491-7872

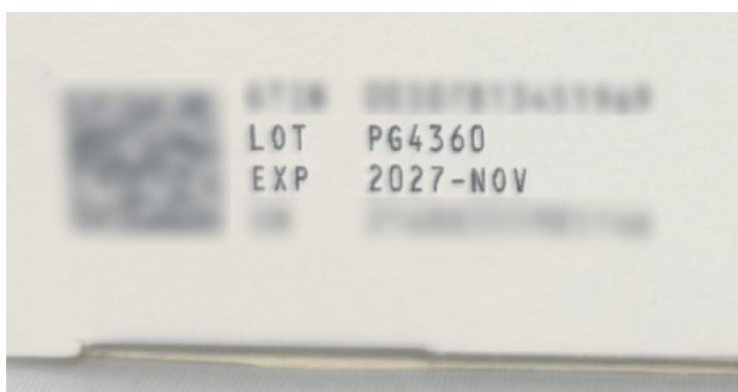
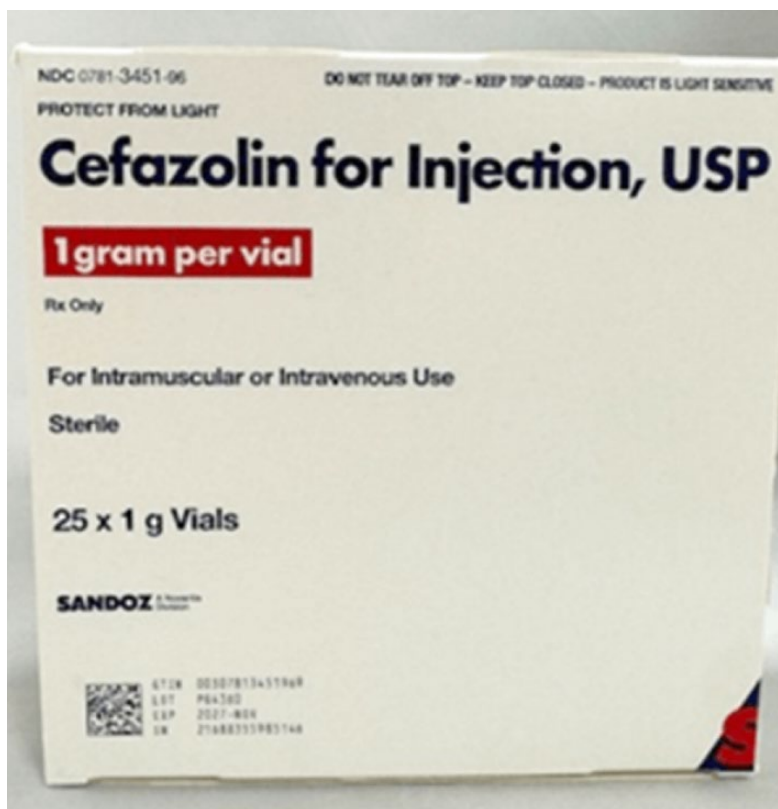
Sandoz6004@sedgwick.com

Media:

Jeanne LaCour
609-955-2339



Product Photos



You may contact our Customer Service Department with any questions or concerns, Monday through Friday, 8:00 am to 5:00 pm, at **1-888-936-7526 (PLAN)**, TDD/TTY 711. Thank you for your continued support of Health Plan of San Joaquin/Mountain Valley Health Plan. 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 <https://www.hpsj.com/>. If you have questions, please contact the Provider Services team at **1.888.936.7526 (PLAN)**.