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.

Recall of Epinephrine Injection, USP 30 mg/ 30 mL

U.S. Food & Drug Administration Publication Date:

09/03/2026

National Drug Code:

0517-3030-01

Product Description:

Epinephrine Injection, USP 30 mg/ 30 mL (1 mg/mL) multi dose vial

Batch (Lot) Number:

25128L1C0, 25280L1C0, 26108L1C0

Expiration Date:

08/2026, 10/2026, 07/2027

Company:

American Regent, Inc.

Questions:

Call American Regent, Inc. Customer Service at 800-645-1706 (8:00AM-6:00PM EST, Monday – Thursday, 8:00AM-4:00PM EST, Friday)

It is for this reason that we are notifying you that on September 3, 2026, the U.S. Food and Drug Administration (FDA) published a drug recall for the following product(s): Epinephrine Injection, USP 30 mg/ 30 mL (1 mg/mL) multi dose vial.

Reason for Recall

American Regent, Inc. is conducting a nationwide voluntary recall of three lots of Epinephrine Injection, USP 30 mg/ 30 mL (1 mg/mL) multi dose vials to the consumer level. Customer complaints were received for leaking and cracked vials, resulting in lack of assurance of sterility. The firm's investigation also revealed the presence of particulate matter identified as Nylon, Cellulosic, Acrylic, Polyethylene and Glass.

Intravenous administration of Epinephrine Injection, USP 30 mg/ 30 mL (1 mg/mL) containing particulate matter may lead to serious adverse health consequences. Particulate matter can cause blockage and clotting in blood vessels, which can cut off blood flow to vital organs, lead to a life-threatening blood clot in the lungs (pulmonary embolism) and cause permanent organ damage or death. Additionally, these particles may cause local vein irritation, inflammatory reaction, aggravation of preexisting infections, and allergic reactions. Additionally, cracked vials can compromise the integrity of the container resulting in loss of sterility and potential contamination which can pose a serious risk for patients. To date, American Regent has not received any reports of adverse events related to this recall.

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.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Product	NDC	Lot	Expiration Date	Distribution Date Range (beginning – end)
Epinephrine Injection, USP	0517-3030-01	25128L1C0	August 2026	September 04, 2025 - December 18, 2025
		25280L1C0	October 2026	December 16, 2025 - April 17, 2026
		26108L1C0	July 2027	June 15, 2026 - July 31, 2026

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/.

REFERENCES:

1. U.S. Food and Drug Administration. (2026). *American Regent, Inc. Issues Voluntary Nationwide Recall of Three Lots of Epinephrine Injection, USP 30 mg/ 30 mL (1 mg/mL) Due to the Presence of Particulate Matter and Lack of Assurance of Sterility*. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/american-regent-inc-issues-voluntary-nationwide-recall-three-lots-epinephrine-injection-usp-30-mg-30