August 5, 2026

PROVIDER ALERT

To:	Health Plan of San Joaquin/Mountain Valley Health Plan ("Health Plan") Practitioners, Facilities, and Hospitals
From:	Health Plan
Type:	Informational/Educational
Subject:	FDA Drug Recall Alert – Papaverine Hydrochloride Injection, USP 60 mg/2 mL
Business:	Medi-Cal Managed Care and Medicare Advantage D-SNP

On July 27, 2026, the Food and Drug Administration (FDA) released a recall announcement on **Papaverine Hydrochloride Injection, USP 60 mg/2 mL**.

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: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/american-regent-inc-issues-voluntary-nationwide-recall-one-lot-papaverine-hydrochloride-injection?utm_medium=email&utm_source=govdelivery#recall-announcement

American Regent, Inc. Issues Voluntary Nationwide Recall of One Lot of Papaverine Hydrochloride Injection, USP 60 mg/ 2 mL Due to the Presence of Visible Particulate Matter

Company Announcement

July 24, 2026 – Shirley, NY, American Regent, Inc. is conducting a nationwide voluntary recall of a single lot of Papaverine Hydrochloride Injection, USP, 60 mg/2 mL single dose vial to the consumer level. The product is being recalled due to the presence of particulate matter identified as glass and/or paraformaldehyde.

Affected Products

Papaverine Hydrochloride Injection, USP Lot # 25202 was distributed nationwide in the United States beginning September 30, 2025. NDC, lot, expiration date and distribution dates can be found on the table below.

Product Name / Strength	Dosage Form / Package	NDC	Lot Number	Expiration Date
Papaverine Hydrochloride Injection, USP	60 mg/2 mL Single dose vial	0517-4002-25	25202	11/30/2026

What to Do

Distributors/retailers/healthcare facilities that have the product which is being recalled should stop using and return to place of purchase or discard the product.

Consumers and healthcare professionals with questions regarding this recall can contact American Regent Inc. using the below information. This product is an intravenous injection and is to be used by or under the direction of a physician. Patients that use this product which is being recalled should stop using them and contact their doctor or health care provider.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Contact Information

American Regent, Inc. Customer Service	Phone: 800-645-1706 (8:00AM-6:00PM EST, Monday – Thursday, 8:00AM-4:00PM EST, Friday)	For detailed return/replacement/credit information
American Regent, Inc. Pharmacovigilance	Phone: 800-734-9236 Email: pv@americanregent.com	To report adverse events
American Regent, Inc. Product Quality Complaints	Phone: 888-354-4855 (9:00AM-5:00PM EST, Monday – Friday) Email: pqc@americanregent.com	For product quality complaints
American Regent, Inc. Medical Information	Phone: 888-354-4855 (9:00AM-5:00PM EST, Monday – Friday) Email: ma@americanregent.com	For medical questions

If you have any further questions, please contact your Provider Services Representative, or call our Customer Service Department at 1-888-936-PLAN (7526). 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 WWW.HPSJ-MVHP.ORG.