

COMPANY 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

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

July 24, 2026

FDA Publish Date:

July 27, 2026

Product Type:

Drugs

Reason for Announcement:

Products were found to contain particulate matter

Company Name:

American Regent, Inc.

Brand Name:

American Regent, Inc.

Product Description:

Papaverine Hydrochloride Injection, USP 60 mg/ 2 mL

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.

Risk Statement: The administration of an injectable product containing particulate matter may result in local irritation or swelling. The particulate matter could travel through and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death. Patients with underlying cardiovascular or pulmonary compromise may be at increased risk. To date, American Regent, Inc. has not received any reports of adverse events related to this recall.

Papaverine is a prescription medication that relaxes smooth muscles and widens blood vessels, primarily used to treat visceral spasms, poor blood circulation, and erectile dysfunction. Papaverine Hydrochloride Injection, USP, is a clear, colorless pale-yellow solution and is available in a 2 mL single-dose vial containing 30 mg/mL

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 Description: Papaverine Hydrochloride Injection, USP 60 mg/2 mL Single dose vial

NDC: 0517-4002-25

Lot#: 25202

Expiration Date: 11/30/2026

Distribution Dates: 9/30/2025

American Regent, Inc. is notifying its distributors and customers by letter and is arranging for return/replacement etc. of all recalled products.

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 Center	Contact Information	Area of Support
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 (mailto: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 (mailto: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 (mailto:ma@americanregent.com)	For medical questions

Adverse reactions or quality problems experienced with the use of this product may 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.htm (<https://www.fda.gov/medwatch/report.htm>).
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm (<https://www.fda.gov/MedWatch/getforms.htm>) 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.

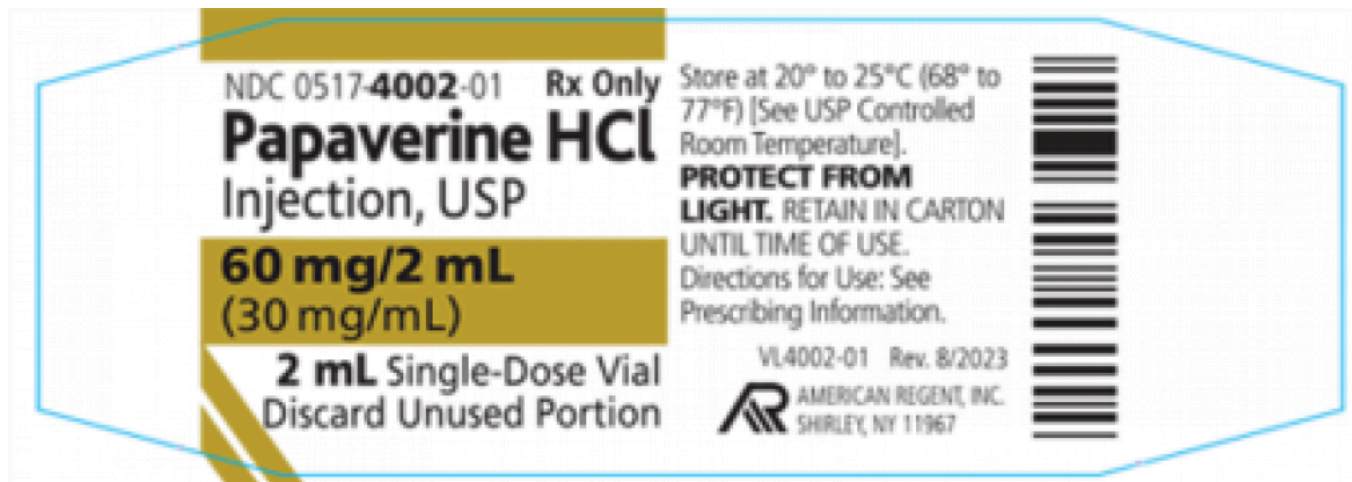
American Regent, Inc. is committed to the safety of patients who rely on its products and is taking this precautionary action to protect public health.

Company Contact Information

Consumers:

☎ (800) 645-1706

Product Photos



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