April 28, 2025

Health Plan of San Joaquin | Mountain Valley Health Plan

To: Health Plan Practitioners, Facilities, and Hospitals
From: Health Plan of San Joaquin/Mountain Valley Health Plan ("Health Plan")
Subject: **FDA Drug Recall Alert - Ropivacaine Hydrochloride Injection USP, 500 mg/100 mL**
Products: Medi-Cal Managed Care

On April 18, 2025, the Food and Drug Administration (FDA) released a recall announcement on **Ropivacaine Hydrochloride Injection USP, 500 mg/100 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 link: Amneal Pharmaceutical LLC Issues a Nationwide Recall of Ropivacaine Hydrochloride Injection, USP 500mg/100mL, Due to the Potential Presence of Particulate Matter | FDA

Amneal Pharmaceutical LLC Issues a Nationwide Recall of Ropivacaine Hydrochloride Injection, USP 500mg/100mL, Due to the Potential Presence of Particulate Matter.

Summary

Company Announcement Date: April 18, 2025
FDA Publish Date: April 18, 2025
Product Type: Drugs
Reason for Announcement: Product may contain an inert fiber identified as polypropylene fibers from the IV bag
Company Name: Amneal Pharmaceuticals LLC.
Brand Name: Amneal Pharmaceuticals LLC.
Product Description: Ropivacaine Hydrochloride Injection, USP, 500mg/100mL IV bag

Company Announcement

FOR IMMEDIATE RELEASE – 04/18/2025 – Bridgewater, NJ, Amneal Pharmaceutical LLC, is recalling two lots of Ropivacaine Hydrochloride Injection, USP, 500mg/100mL, Infusion bags to the hospital/user level as the products may contain an inert fiber identified as polypropylene fibers from the IV bag.

Risk Statement: Introduction of polypropylene particulates into the epidural space (or inadvertent administration into the intrathecal space) may result in a variety of adverse events. There is a reasonable probability that particulate matter in the epidural space may cause an epidural inflammatory process to meningitis or potentially damage the spinal cord. Administered intrathecally, particulate matter could result in inflammation, hydrocephalus (water on the brain), which could lead to embolization and organ damage.

To date, Amneal Pharmaceuticals has received no reports of adverse events or injuries related to this recall.

The recalled product was distributed nationwide to wholesalers/distributors between the dates of 04/23/2024 to 11/8/2024 only.

The product is indicated for the production of local or regional anesthesia for surgery and or acute pain management and is packaged in 12x100mL Single Dose IV bags (NDC 70121-17343). The affected Ropivacaine Hydrochloride Injection, USP, 500mg/100mL, products are Lot AL240003 (exp 01/2026) and Lot AL240004 (exp 01/2026). No other Ropivacaine Hydrochloride Injection, USP lots are impacted.

Amneal is notifying its customers by UPS and is arranging for return of all recalled products. Wholesalers/distributors are asked to notify their hospital/ user customers of the recall and provide instruction to contact Amneal for the return of the recalled products to Amneal.

Hospitals/users with questions regarding this recall can contact Amneal Pharmaceuticals by:
Phone: 833-582-0812 Monday-Friday, 8:00 am-5:00 pm, EST
Fax: 631-983-2595
E-mail to: RopivacaineHCl-Recall@amneal.com

For Medical Inquiries or to report Adverse Events, or quality problems experienced with the use of this product, please contact Amneal Drug Safety by phone at 1-877-835-5472, Monday - Friday, 8:00 am – 6:00 pm, EST, or e-mail at DrugSafety@amneal.com.

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
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1800-332-1088 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:

Amneal Drug Safety
1-877-835-5472

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)**.