Central Admixture Pharmacy Services (CAPS) Issues Nationwide Recall of Phenylephrine 40 mg added to 0.9% Sodium Chloride 250 mL in 250 mL Excel Bags due to Visible Black Particulate Matter in a Single-Sealed Vial

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FOR IMMEDIATE RELEASE – February 25, 2025 – Bethlehem, PA. Central Admixture Pharmacy is recalling three lots of Phenylephrine 40 mg added to 0.9% Sodium Chloride 250 mL in 250 mL Excel Bags (NDC: 71285-6092-1) to the hospital level. The product is being recalled because CAPS was notified by their raw material supplier of the detection of visible black particulate matter in a single sealed vial of Phenylephrine Hydrochloride.

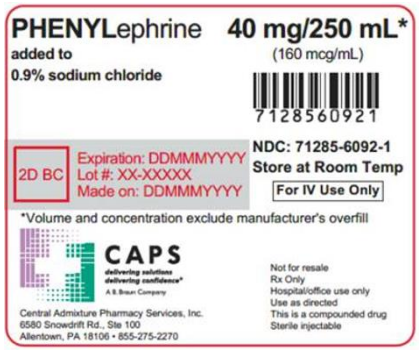
Risk Statement: Administration of an injectable product containing particulate matter may cause local irritation or swelling as a response to the foreign material. If the particulate matter enters the blood vessels, it can travel to various organs and potentially blocking blood vessels in the heart, lungs or brain, leading to serious complications such as stroke or even death. To date, CAPS has not received any reports of adverse events or injuries associated with this recall.

Affected Product:

NDC	Product Description	Lot #	Expiration Date	Distribution Dates	Region Distributed
71285-6092-1	Phenylephrine 40 mg added to 0.9% Sodium Chloride 250 mL in 250 mL Excel Bag	37-928390	03MAR2025	17 Dec 2024	United States
71285-6092-1	Phenylephrine 40 mg added to 0.9% Sodium Chloride 250 mL in 250 mL Excel Bag	37-928796	09MAR2025	26 Dec 2024	United States
71285-6092-1	Phenylephrine 40 mg added to 0.9% Sodium Chloride 250 mL in 250 mL Excel Bag	37-928839	10MAR2025	03 Jan 2025 – 08 Jan 2025	United States

CAPS drug product is packaged in 0.9% Sodium Chloride 250 mL in 250 mL Excel Bag. The product can be identified by the sample label below, the NDC format for

products compounded at Lehigh Valley is "**71285-XXXX-X**." The lot number format is "**37-XXXXXX**."



CAPS is notifying its distributors and customers by USPS certified mail and is arranging for return. By completing a "Urgent Pharmaceutical Recall Response Form" and either faxing the form to (610) 849-1197 or e-mail to recalls@bbraunusa.com within two (2) weeks of receipt, even if the total inventory in the customer's possession is zero (0).

Consumers with questions regarding this recall can contact CAPS by calling 1-844-903-6417. 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.
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 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.