

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

This is to inform you that the following Lot No.'s 24418, 25131, and 25349 of the product manufactured and distributed by American Regent, Inc. is the subject of a Recall. Recall of this product to RETAIL LEVEL was initiated due to particulate found during Reject Characterization.

Acetylcysteine, administered orally, is indicated as an antidote to prevent or lessen hepatic injury which may occur following the ingestion of a potentially hepatotoxic quantity of acetaminophen. Acetylcysteine, as a mucolytic agent for inhalation, is indicated as adjuvant therapy for patients with abnormal, viscid, or inspissated mucous secretions in such conditions as: Chronic bronchopulmonary disease (chronic emphysema, emphysema with bronchitis, chronic asthmatic bronchitis, tuberculosis, bronchiectasis, and primary amyloidosis of the lung) Acute bronchopulmonary disease (pneumonia, bronchitis, tracheobronchitis), Pulmonary complications of cystic fibrosis, Tracheostomy care, Pulmonary complications associated with surgery, Use during anesthesia, Post-traumatic chest conditions, Atelectasis due to mucous obstruction, Diagnostic bronchial studies (bronchograms, bronchspirometry, and bronchial wedge catheterization).

Because Acetylcysteine Solution is administered via inhalation or oral routes, these routes of administration are generally associated with a lower risk of clinically significant complications resulting from the presence of particulate matter. It is likely any particle missed by visual inspection will be removed by non-specific chemical or physical interaction of the particle in the admixture with the delivery device for inhalation administration or by mucociliary clearance mechanisms or digestion in the stomach for oral administration. As of July 24, 2026, American Regent, Inc. has not received any reports of adverse events related to this recall.

PRODUCT: Acetylcysteine Solution, USP 10% (100 mg/mL) 4 mL/vial

NDC NUMBER: 0517-7504-25

Lot No: 24418

Expiration Date: November 30, 2026

Lot No: 25131

Expiration Date: March 31, 2027

Lot No: 25349

Expiration Date: August 31, 2027