Acetylcysteine Solution, USP (Roxane Laboratories, Inc.): Recall - Visible Glass Particle

U.S. Food & Drug Administration

AUDIENCE: Risk Manager, Pulmonology, Patient

ISSUE: Bedford Laboratories issued an update to the voluntary recall, initiated December 20, 2011 of one lot of Acetylcysteine Solution (Roxane Laboratories) due to the discovery of a single visible glass particle in a vial within the lot. Glass particles can cause airway obstruction resulting in symptoms of choking, wheezing, difficulty breathing, coughing and potentially hemoptysis. Use of an inhaled product with glass particles has the potential to cause choking which could be life-threatening. Aerosolization of small glass particles in the airways could result in recurrent infections (due to obstruction of airways, and decreased clearance of airway secretions).

BACKGROUND: The single lot is identified as Lot 1877093 – Exp. Date June 2013. Acetylcysteine is indicated as adjuvant therapy for patients with abnormal, viscid, or inspissated mucous secretion. 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 for inhalation is usually delivered via a Nebulizer, but can also be delivered via direct instillation into a tracheostomy, or into the bronchial-pulmonary tree during bronchosopy.

RECOMMENDATION: Hospitals, emergency rooms, clinics, physician offices and other healthcare facilities and providers should not use the product lot listed above for patient care and should immediately quarantine any product for return. Patients that may have received product dispensed from this one lot should return the product to their pharmacist.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] 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

[02/02/2012 - Press Release [3] - Bedford Laboratories]

SOURCE [4]

Source URL (retrieved on *04/16/2014 - 7:42pm*):
http://www.mdtmag.com/news/2012/02/acetylcysteine-solution-usp-roxane-laboratories-inc-recall-visible-glass-particle?qt-most_popular=0

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Safety/Recalls/ucm290204.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm290219.htm