Bedford Laboratories Polymyxin B For Injection USP And Vecuronium Bromide For Injection: Recall - Glass Particles

U.S. Food & Drug Administration

AUDIENCE: Pharmacy, Risk Manager

ISSUE: Bedford Laboratories issued guidance on the nationwide voluntary product recalls originally issued on August 2, 2011. The recalls were initiated after the discovery of a visible glass particle in a limited number of vials within the lots listed below to the user level.

- Polymyxin B for Injection USP, 500,000 Units per vial – NDC #55390-139-10 Lot 1942980 – Exp. Date August 2013 and Lot 1895027 – Exp. Date June 2013
- Vecuronium Bromide for Injection, 10 mg per vial – NDC #55390-037-10 Lot 1865067 – Exp. Date May 2012
- Vecuronium Bromide for Injection, 20 mg per vial – NDC #55390-039-10 Lot 1865069 – Exp. Date February 2012

Particulate matter in injections can be harmful when introduced into the bloodstream. Potential adverse events after intravenous administration may include vein irritation and phlebitis, pulmonary dysfunction and granulomas, local tissue infarction, occlusion of capillaries and arteries, anaphylactic shock, and death. The introduction of particulate matter via the intrathecal route into the cerebrospinal fluid may serve as a nidus for the development of chemical meningitis. Introduction of a foreign body to the eye via topical or subconjuntive routes can cause corneal abrasion/laceration, lacrimal tear and general irritation. To date, there have been no reports of adverse events for the lots being recalled.

BACKGROUND: Polymyxin B is indicated in the treatment of acute infections caused by susceptible strains of Pseudomonas aeruginosa. Vecuronium Bromide is indicated as an adjunct to general anesthesia, to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

RECOMMENDATION: Hospitals, emergency rooms, clinics, physician offices and other healthcare facilities and providers should not use the product lots listed above for patient care and should immediately quarantine any product for return.

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

[01/10/2012 - Press Release [3] - Bedford Laboratories]
[01/11/2012 - Product Photos [4] - FDA]

SOURCE [5]

Source URL (retrieved on *11/25/2014 - 5:31pm*):
http://www.mdtmag.com/news/2012/01/bedford-laboratories-polymyxin-b-injection-usp-and-vecuronium-bromide-injection-recall-glass-particles

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/ucm286953.htm
[4] http://www.fda.gov/Safety/Recalls/ucm287028.htm
[5] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm287411.htm