

March 21, 2010

FDA Safety Announcement: American Regent Injectable Products: Recall - Visible Particulates in Products



AUDIENCE: Pharmacy

ISSUE: Recall issued due to some vials exhibiting translucent visible particulate matter consistent with that of glass. As a result, there exists the possibility for adverse events following intravenous administration which include: damage to blood vessels in the lung, localized swelling, and granuloma formation.

BACKGROUND: Glass delamination (separation) can occur with high PH solutions when the surface glass from the vial separates into thin layers, resulting in glass particles with a flaky appearance.

RECOMMENDATION: Hospitals, Home Health Care Agencies, Emergency Rooms, Infusion Centers, Clinics and other healthcare facilities should not use the recalled American Regent products. Recalled products should be immediately quarantined for return. Please refer to the Press Releases below for specific lot numbers recalled.

[03/16/2011 - [Press Release](#)³, Dexamethasone Sodium Phosphate - American Regent]

[03/15/2011 - [Press Release](#)⁴, Bacteriostatic Sodium Chloride - American Regent]

[03/15/2011 - [Press Release](#)⁵, Concentrated Sodium Chloride - American Regent]

[02/04/2011 - [Press Release](#)⁶, Sodium Thiosulfate - American Regent]

[02/03/2011 - [Press Release](#)⁷, Potassium Phosphates - American Regent]

Previous, related product alerts:

[12/24/2010 - [Dexamethasone Sodium Phosphate Injection](#)⁸]

[12/29/2010 - [Sodium Bicarbonate Injection](#)⁹]

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

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- [Download form](#) 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

Read the MedWatch safety alert, including a link to the FDA recall notice, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm242365.htm>

###

www.kcercoalition.com/alerts.htm