

December 29, 2010

FDA Safety Announcement: American Regent Initiates Nationwide Voluntary Recall of Sodium Bicarbonate Injection, USP 7.5% and 8.4%, 50mL Single Dose Vials Due to Particulate Matter



AUDIENCE: Hospital Risk Managers, Pharmacy, Emergency Medicine

ISSUE: American Regent has issued a voluntary recall of Sodium Bicarbonate Injection, USP 7.5% and 8.4%, 50 mL Single Dose Vials because some vials may contain particulates. Potential adverse events after intravenous administration include damage to blood vessels in the lung, localized swelling, and granuloma formation. American Regent is undertaking this recall in consideration of the potential for safety issues if any of the following lots of product are administered to patients.

American Regent Recall Lots of Sodium Bicarbonate Injection, USP

Sodium Bicarbonate Injection, USP, 7.5%, 44.6 mEq/50 mL, Single Dose Vial NDC # 0517-0639-25

<u>Lot</u>	<u>Expire Date</u>
8833	Dec-2010
9130	Feb-2011
9342	May-2011
9543	Aug-2011
9702	Oct-2011
0068	Feb-2012
0276	Apr-2012
0581	Aug-2012
0745	Nov-2012

Sodium Bicarbonate Injection, USP, 8.4%, 50 mEq/50 mL Single Dose Vial NDC # 0517-1550-25

<u>Lot</u>	<u>Expire Date</u>
8845	Dec-2010
9062	Jan-2011
9058	Feb-2011
9111	Feb-2011
9128	Feb-2011
9158	Mar-2011
9180	Mar-2011
9212	Mar-2011
9262	Apr-2011
9271	Apr-2011
9292	Apr-2011
9346	May-2011
9346A	May-2011

www.kcercoalition.com/alerts.htm

9360	May-2011
9374	May-2011
9396	Jun-2011
9412	Jun-2011
9438	Jun-2011
9720	Oct-2011
9801	Nov-2011
9821	Nov-2011
0054	Jan-2012
0115	Feb-2012
0162	Mar-2012
0172	Mar-2012
0237	Apr-2012
0427	Jun-2012
0528	Aug-2012
0597	Sep-2012
0649	Sep-2012

BACKGROUND: Sodium Bicarbonate Injection, USP, is indicated in the treatment of metabolic acidosis which may occur in severe renal disease, uncontrolled diabetes, circulatory insufficiency due to shock or severe dehydration, extracorporeal circulation of blood, cardiac arrest and severe primary lactic acidosis. Sodium bicarbonate is further indicated in the treatment of certain drug intoxications, including barbiturates (where dissociation of the barbiturate-protein complex is desired), in poisoning by salicylates or methyl alcohol and in hemolytic reactions requiring alkalization of the urine to diminish nephrotoxicity of blood pigments. Sodium bicarbonate is also indicated in severe diarrhea which is often accompanied by a significant loss of bicarbonate.

RECOMMENDATION: Hospitals, infusion centers, clinics and other healthcare facilities should not use American Regent Inc., Sodium Bicarbonate Injection, USP, 7.5% and 8.4%, 50 mL Single Dose Vials with the lot #s on the above list for patient care and should immediately quarantine any product for return.

American Regent is notifying its distributors and consumers by email, facsimile and/or overnight courier and is arranging for return of all recalled product. Consumers/distributors/retailers that have product which is being recalled should stop use. American Regent will credit accounts for all returned product with these lot #'s. Those with questions about the return process, please call our Customer Service Department at **1-800-645-1706**: Monday thru Friday from 8:30AM to 7:00PM ET. Hospitals, infusion centers, clinics and healthcare providers, or patients with other questions may contact the Professional Services Department at **800-645-1706**.

ADVERSE REPORTS:

Any adverse reactions experienced with the use of this product, and/or quality problems should be reported to American Regent, Inc. **via email at PV@luitpold.com, by fax to 610-650-7781 or 610-650-0170 or by phone at 1-800-734-9236.** Additionally, adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's **[MedWatch Adverse Event Reporting program online](#)** or by regular mail sending postage-paid **[FDA Form 3500](#)** to Medwatch at 5600 Fishers Lane Rockville, MD 20857 or by fax at **1-800-FDA-0178**.

Read the complete FDA recall notice, at:
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm238323.htm>