



Missouri Department of Health and Senior Services Advisory Alert

The Missouri Department of Health and Senior Services received the following news release regarding recalling 5 lots of Vasopressin Injection.

American Regent, Inc. Initiates Voluntary Recall of Seventeen Lots of Vasopressin Injection, USP, Multiple Dose Vials Due to Sub-Potency

Contact:

Consumer:
1-877-788-3232

Media:

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FOR IMMEDIATE RELEASE - August 2, 2011 - Shirley, NY - American Regent, Inc. is conducting a nationwide voluntary recall of 5 lots of Vasopressin Injection, USP 20 units/mL (200 units/10mL), 10 mL Multiple Dose Vials; 11 lots of Vasopressin Injection, USP 20 units/mL, 1 mL Multiple Dose Vials; and 1 lot of Vasopressin Injection, USP 10 units/0.5 mL, 0.5 mL Multiple Dose Vials to the Retail/Hospital level. Recall of this product was initiated by American Regent, Inc. because some vials may not maintain potency throughout their shelf-life.

Potential adverse events after administration of solutions that are below potency limits may include reduced effectiveness. American Regent, Inc. has received no reports of adverse events related to reduced effectiveness for Vasopressin Injection, USP of the lots being recalled during the time period January 1, 2009 to July 27, 2011.

Vasopressin Injection, USP is indicated for prevention and treatment of postoperative abdominal distention, in abdominal roentgenography to dispel interfering gas shadows, and in diabetes insipidus. Below are the product sizes and lots affected. The product was distributed to wholesalers and distributors nationwide.

Vasopressin Injection, USP 20 units/mL (200 units/10 mL), 10 mL multiple dose vial,
Package Size: 10, NDC # 0517-0410-10

Lot #	Exp Date	Exp Period
9677	October 2011	24 Months
0052	January 2012	24 Months
0294	October 2011	18 Months
0442	December 2011	18 Months
0663	April 2012	18 Months

Vasopressin Injection, USP 20 units/mL, 1 mL multiple dose vial,
Package Size: 25, NDC # 0517-1020-25

Lot #	Exp Date	Exp Period
9532	August 2011	24 Months
9618	September 2011	24 Months
9707	October 2011	24 months
0104	February 2012	24 months
0124	February 2012	24 months
0273	October 2011	18 months
0346	November 2011	18 months
0400	December 2011	18 months
0437	December 2011	18 months
0618	March 2012	18 months
0758	May 2012	18 months

Vasopressin Injection, USP 10 units/0.5 mL, 0.5 mL multiple dose vial
Package Size: 25, NDC # 0517-0510-25

Lot #	Exp Date	Exp Period
0103	February 2012	24 Months

Hospitals, infusion centers, clinics, retail pharmacies and other healthcare facilities should not use American Regent, Inc., Vasopressin Injection, USP Multiple Dose Vials with the lot #s listed above for patient care and should immediately quarantine any product for return to American Regent Inc.

American Regent, Inc. will credit accounts for all returned product with these lot #s. Those with questions about the return or recall process, please call our Customer Service Department at 1-877-788-3232: Monday thru Friday from 8:30 AM to 7:00 PM EDT.

Hospitals, infusion centers, clinics, retail pharmacies and other healthcare facilities with product quality complaints, medical or other questions concerning the use of the product or reasons for this recall should contact the Professional Services Department at 1-877-788-3232: Monday thru Friday from 9:00 AM to 5:00 PM EDT.

Any adverse reactions experienced with the use of this product should be reported to American Regent, Inc. via e-mail at pv@luitpold.com, by fax to (610) 650-0170, or by phone at 1-800-734-9236: Monday thru Friday from 9:00 AM to 5:00 PM EDT. TO EXPEDITE HANDLING, PLEASE DO NOT REPORT ANYTHING OTHER THAN SPECIFIC ADVERSE EVENTS TO THIS E-MAIL ADDRESS OR FAX OR PHONE.

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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, by regular mail, or by fax.

- Online: www.fda.gov/medwatch/report.htm¹

- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm². Mail to address on the pre-addressed form. · Fax: 1-800-FDA-0178.

This voluntary recall is being conducted with the knowledge of the U.S. Food & Drug Administration. Vasopressin Injection, USP is manufactured by Luitpold Pharmaceuticals, Inc. and is distributed by American Regent, Inc. (Shirley, NY). Source: Luitpold Pharmaceuticals, Inc.

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