

**Epinephrine Injection, USP, 1:1000, 1 mL Ampules Lot #1395, Exp Date: July 2012 (4/12)**

**FOR IMMEDIATE RELEASE** - April 24, 2011 - American Regent is conducting a nationwide voluntary recall to the Retail/Hospital level of the following product:

**Epinephrine Injection, USP, 1:1000, 1 mL Ampules  
NDC #0517-1071-25**

**Lot #1395, Exp Date: July 2012**

**PLEASE NOTE:** This recall, initiated on April 24, 2012 to the Retail/Hospital Level, is for lot #1395 only. **No other lot or sizes of Epinephrine Injection, USP are subject to this voluntary recall.**

American Regent is undertaking this voluntary recall of Epinephrine Injection, USP, lot #1395 because of discoloration and small visible particles found in some ampules of this lot.

Potential adverse events after intravenous administration of solutions containing particulates may include disruption of blood flow within small blood vessels in the lung, localized inflammation (swelling and redness), and granuloma formation. Muscle and adipose tissue damage may occur by the intramuscular or subcutaneous injection of solutions containing particulates. Adverse events with intra-spinal injection for this product containing particles are unknown, but may cause inflammation. Adverse events after topical ocular administration with Epinephrine solutions containing particles are also unknown, but may result in ocular pain or irritation.

Epinephrine Injection, USP is indicated to relieve respiratory distress due to bronchospasm, to provide rapid relief of hypersensitivity reactions to drugs and other allergens, and to prolong the action of infiltration anesthetics. Its cardiac effects may be of use in restoring cardiac rhythm in cardiac arrest due to various causes, but it is not used in cardiac failure or in hemorrhagic, traumatic, or cardiogenic shock.

Epinephrine Injection, USP is used as a hemostatic agent. It is also used in treating mucosal congestion of hay fever, rhinitis, and acute sinusitis; to relieve bronchial asthmatic paroxysms; in syncope due to complete heart block or carotid sinus hypersensitivity; for symptomatic relief of serum sickness, urticaria, angioneurotic edema; for resuscitation in cardiac arrest following anesthetic accidents; in simple (open angle) glaucoma; for relaxation of uterine musculature and to inhibit uterine contractions. Epinephrine Injection can be utilized to prolong the action of intraspinal and local anesthetics.

The product was distributed to wholesalers and distributors nationwide. Hospitals, Retail Pharmacies, Clinics, Physician Offices, and other healthcare facilities and providers should not use American Regent Epinephrine Injection, USP, 1:1000, 1 mL ampules with lot #1395 for patient care and should immediately quarantine any product for return.

American Regent is notifying its distributors and consumers by e-mail, 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 Epinephrine Injection, USP, 1:1000, 1 mL ampules with lot #1395. 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 ET.

Hospitals, emergency rooms, clinics, and other healthcare facilities and providers, or patients 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 ET.

Any adverse reactions experienced with the use of this product should be reported to American Regent via e-mail at [pv@luitpold.com](mailto: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 ET. TO EXPEDITE HANDLING PLEASE DO NOT REPORT ANYTHING OTHER THAN SPECIFIC ADVERSE EVENTS TO THIS E-MAIL ADDRESS OR FAX OR PHONE.

Adverse reactions or quality problems experienced with the use of this product/lot 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.htm](http://www.fda.gov/medwatch/report.htm)<sup>1</sup>
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)<sup>2</sup>. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

While American Regent continues to investigate this issue, the company is taking precautionary action and initiated this voluntary recall. American Regent has informed the FDA of its actions and is maintaining ongoing discussions with the Agency.

Epinephrine Injection, USP is manufactured by Luitpold Pharmaceuticals, Inc. and is distributed by American Regent, Inc. (Shirley, NY).

Source: Luitpold Pharmaceuticals, Inc.

This voluntary recall is being conducted with the knowledge of the U.S. Food and Drug Administration.