Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 15, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Hospira, Inc. - RECALL [Drug]

AFFECTED PRODUCT: **Dobutamine Injection, USP, 250 mg, 20 mL, Single-dose fliptop vial**

SUMMARY: **Unclassified Recall; The recall was due to a confirmed customer report of discolored solution.**

The recalled product is one lot of Dobutamine Injection, USP, 250 mg, 20 mL, Single-dose fliptop vial, (NDC 0409-2344-02), Lot 27-352-DK. (NDC and lot number can be found on the right-hand side of the primary label).

This lot was distributed nationwide to distributors/wholesalers, hospitals and clinics from August 2013 through September 2013.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-877-907-9956 (M-F, 8 a.m - 5 p.m. ET).**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Hospira Announces Voluntary Nationwide Recall Of One Lot Of Dobutamine Injection, USP, 250 MG, 20 ML, Single-Dose Fliptop Vial, Due To Visible Particulates

Contact:
Consumer:
800-615-0187

Media:
224-212-2357

FOR IMMEDIATE RELEASE - May 14, 2014 - Hospira, Inc. (NYSE: HSP), on Jan. 10, 2014, issued a nationwide recall to the user level for one lot of Dobutamine Injection, USP, 250 mg, 20 mL, Single-dose fliptop vial, (NDC 0409-2344-02), Lot 27-352-DK. (NDC and lot number can be found on the right-hand side of the primary label). The recall was due to a confirmed customer report of discolored solution. Upon review of the complaint, a chip in the glass at the neck of the vial was identified as well as glass particulate within the solution. The discoloration of the solution may have resulted either from contamination of the solution or more likely, oxidation, as dobutamine is oxygen sensitive. To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

Risk factors associated with particulate and/or a glass defect include the potential for particulate to be injected, a breach of sterility/contamination of the vial contents, leakage of contents, and/or a delay in therapy.

In general, injected particulate matter may result acutely in local inflammation, phlebitis, and/or low level allergic response through mechanical disruption of tissue or immune response to the particulate. Small capillaries may become obstructed. Chronically, following sequestration, some granuloma formation in the lungs is possible. A loss of sterility is a primary concern when a container has a leak, since an open pathway exists for contamination of fluid. If contaminated solution is used on a patient, this may potentially cause bacteremia, sepsis, septic shock and endocarditis, and death may result. Signs and symptoms could include redness, pain, swelling at the site, fever, shortness of breath, tachycardia, nausea, and vomiting. Septicemia could lead to shock and multisystem organ failure, requiring critical medical intervention. Leakage may result in drug wastage, spillage onto equipment, flooring and personnel. Dobutamine should be considered a potent drug and potentially irritating to eyes and respiratory tract. Users should avoid liquid aerosol generation and skin contact. If a defective vial is not detected until the point of care, there may be a delay in therapy. If used in a critical care setting, a delay in therapy could theoretically result in worsening cardiac status.

This lot was distributed nationwide to distributors/wholesalers, hospitals and clinics from August 2013 through September 2013. Hospira was unable to determine root cause, but recalled the entire lot as a precautionary measure. The issue wasn't found in any retained samples from the lot.

Anyone with an existing inventory should immediately stop use and quarantine any affected product. In addition, customers should inform potential users of this product in their organizations of this notification. For additional assistance, call Stericycle at 1-877-907-9956 (M-F, 8 a.m - 5 p.m. ET).

For medical inquiries, please contact Hospira Medical Communications at 1-800-615-0187. This phone number is available 24 hours a day, seven days a week.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm 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

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

About Hospira

Hospira, Inc. is the world's leading provider of injectable drugs and infusion technologies, and a global leader in biosimilars. Through its broad, integrated portfolio, Hospira is uniquely positioned to Advance Wellness™ by improving patient and caregiver safety while reducing healthcare costs. The company is headquartered in Lake Forest, Ill., and has approximately 17,000 employees. Learn more at www.hospira.com.

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