Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 19, 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: **Labetalol Hydrochloride Injection, USP, 100 mg/20 mL (5 mg/mL) 20 mL Multidose Vial.**

SUMMARY: **Unclassified Recall; The recall is due to a confirmed customer report of embedded particulate within the glass vial and visible particles floating in the solution.**

Labetalol Hydrochloride Injection, USP, 100 mg/20 mL (5 mg/mL) 20 mL Multidose Vial, NDC 0409-2267-20, Lot 36-225-DD, Expiration 12/01/2015. (NDC and lot number can be found on the right-hand side of the primary label). The product is packaged in a 20 mL multidose glass vial, each vial is packaged within an individual carton, and 50 individual cartons are packaged within each shipping container.

The recalled lot was distributed nationwide in the U.S. in February, 2014, to wholesalers/distributors, hospitals and clinics.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-888-386-2076 (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 Labetalol Hydrochloride Injection, USP, 100 MG/20 ML (5MG/ML), 20 ML, Multidose Vial, Due To Visible Particulates

Contact:
Consumer::
1-800-615-0187
Media:
224-212-2357

FOR IMMEDIATE RELEASE - May 16, 2014 - Hospira, Inc. (NYSE: HSP), announced today it will initiate a voluntary nationwide recall to the user level for one lot of Labetalol Hydrochloride Injection, USP, 100 mg/20 mL (5 mg/mL) 20 mL Multidose Vial, NDC 0409-2267-20, Lot 36-225-DD, Expiration 12/01/2015. (NDC and lot number can be found on the right-hand side of the primary label). The recall is due to a confirmed customer report of embedded particulate within the glass vial and visible particles floating in the solution. Based upon the complaint sample analysis, there is the potential for product to come into contact with embedded particles and the particles may become dislodged into the solution. The embedded particulate was identified as stainless steel and the floating particulate as iron oxide. To date, Hospira has not received reports of any adverse events associated with this issue for this lot. Hospira has attributed the embedded particulate to a supplier's glass defect. As a result of this issue, Hospira is working with its supplier on implementing corrective and preventive actions.

If the particulate is administered undetected - the health implications will vary depending on the amount of particulate matter injected into the patient, the size of the particles, the patient's underlying medical condition and heart abnormalities. Blocked administration of the drug to the patient, causing a delay in therapy is possible. However, due to the size of the particulates identified, it is more likely that particulates are able to pass through the catheter and may cause injection site reactions and local irritation in the blood vessels, tissues and organs. While extremely rare, particulate exposed to strong magnetic fields (e.g. MRI), could potentially dislodge and cause tissue damage. However, due to the particulate size identified, the probability of an adverse outcome resulting from such particulate when dislodged through a magnetic field is remote.

Labetalol Hydrochloride Injection, USP is a clear colorless solution for intravenous administration and is indicated for control of blood pressure in severe hypertension. The product is packaged in a 20 mL multidose glass vial, each vial is packaged within an individual carton, and 50 individual cartons are packaged within each shipping container. The recalled lot was distributed nationwide in the U.S. in February, 2014, to wholesalers/distributors, hospitals and clinics.

Hospira is notifying its distributors and customers by issuing a recall notification letter and will arrange for return/replacement of all recalled product. 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 1-888-386-2076 (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. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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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