Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: June 18, 2014

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Hospira, Inc. [Drug]

AFFECTED PRODUCT: **0.5% Marcaine™ (Bupivacaine HCl Injection, USP)**

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

The recalled product is one lot of 0.5% Marcaine™ (Bupivacaine HCl Injection, USP), 30 mL, Single-dose Vial – Preservative Free (NDC 0409-1560-29), Lot 33-545-DD. Marcaine is packaged 10 units per carton/100 units per case in glass fliptop vials.

The recalled product was distributed November 2013 through March 2014 to wholesalers/distributors, hospitals and clinics nationwide.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-888-656-6380 (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 0.5% Marcaine™ (Bupivacaine HCl Injection, USP), 30 ML, Single-Dose, Preservative-Free Vial Due to Visible Particulates

Contact
Consumer:
1-800-615-0187

Media:
224-212-2357

FOR IMMEDIATE RELEASE - June 17, 2014 - Hospira, Inc. (NYSE: HSP), announced today it will initiate a voluntary nationwide recall to the user level for one lot of 0.5% Marcaine™ (Bupivacaine HCl Injection, USP), 30 mL, Single-dose Vial – Preservative Free (NDC 0409-1560-29), Lot 33-545-DD. The recall is due to a confirmed customer report of particulate embedded in the glass vial as well as visible particulate in the solution. 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. Hospira is working with its supplier on implementing corrective and preventive actions.

If the particulate goes undetected and solution is administered - depending on the particle size and number - it could block administration of the drug to the patient, causing a delay in therapy. However, this is an unlikely outcome due to the size of the subvisible particulates identified. It is more likely that particulates are able to pass through the catheter and may result in local inflammation, mechanical disruption of tissue or immune response to the particulate.

While extremely rare, particulate exposed to strong magnetic fields (e.g. MRI), could potentially dislodge and cause tissue damage. However, the particulate size identified is considered too small. Therefore, an adverse outcome is extremely unlikely.

Marcaine is packaged 10 units per carton/100 units per case in glass fliptop vials. The impacted lot of Marcaine was distributed November 2013 through March 2014 to wholesalers/distributors, hospitals and clinics nationwide.

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. Hospira will be notifying its direct distributors/customers via a recall letter and will arrange for impacted product to be returned to Stericycle for returns processing. For additional assistance, call Stericycle at 1-888-656-6380 (M-F, 8 a.m. - 5 p.m. ET).

For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Complaint Management	1-800-441-4100 (8am-5pm CT, M-F) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 or medcom@hospira.com (Available 24 hours a day/7 days per week)	Medical inquiries

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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