



**Indiana State
Department of Health**
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 21, 2013

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

FROM: *A. Scott Gilliam*
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Hospira Inc Recall [Drug]

AFFECTED PRODUCT: One Lot of 0.25% Marcaine™ (Bupivacaine HCL Injection, USP), 75mg/30ml, Single-Dose - Preservative Free Vial Due to Presence of Particulate Matter

SUMMARY: Unclassified Recall; Hospira, Inc. (NYSE: HSP), announced today it will initiate a voluntary nationwide recall to the user level for one lot of 0.25% Marcaine™ (Bupivacaine HCl Injection, USP), 75 mg/30 mL, Single-dose Vial – Preservative Free (NDC 0409-1559-30), Lot 25-220-DD. The recall is due to a confirmed customer report of discolored solution with visible particles inside the glass vial as well as embedded in the glass. The embedded particulate was identified as iron oxide measuring approximately 3mm in diameter. If the particulate goes undetected and solution is administered, the particle may potentially block the infusion of the solution to the patient, resulting in a delay in therapy. Iron particulate may put a patient at risk from MRI (strong magnetic field exposure) as metal particulate, could potentially dislodge and be pulled through tissue causing inflammation and tissue trauma. The administration of an injectable with the presence of foreign particulates may potentially cause thrombophlebitis, bacteremia, sepsis, and/or endocarditis and death may result. Signs and symptoms could include redness, pain, swelling at the site, fever, shortness of breath, tachycardia, nausea, and vomiting.

SUGGESTED ACTION: Marcaine is packaged 10 units per carton/100 units per case in glass fliptop vials. The impacted lot of Marcaine was distributed August 2013 through October 2013 to wholesalers/distributors, hospitals and pharmacies. Anyone with an existing inventory should immediately stop use and quarantine any affected product and return the product to Stericycle. For additional assistance, call Stericycle at 1-866-891-1984 between 8 a.m. and 5 p.m., ET, Monday through Friday. Furthermore, if any recalled products are found, please notify this office at 317-233-3213.

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 Issues a Voluntary Nationwide Recall of One Lot of 0.25% Marcaine™ (Bupivacaine HCL Injection, USP), 75mg/30ml, Single-Dose - Preservative Free Vial Due to Presence of Particulate Matter

Contact:

Consumer:
(866) 891-1984

Media:
(224) 212-2357

FOR IMMEDIATE RELEASE - LAKE FOREST, ILL., - Oct. 18, 2013 - Hospira, Inc. (NYSE: HSP), announced today it will initiate a voluntary nationwide recall to the user level for one lot of 0.25% Marcaine™ (Bupivacaine HCl Injection, USP), 75 mg/30 mL, Single-dose Vial – Preservative Free (NDC 0409-1559-30), Lot 25-220-DD. The recall is due to a confirmed customer report of discolored solution with visible particles inside the glass vial as well as embedded in the glass. The embedded particulate was identified as iron oxide measuring approximately 3mm in diameter. 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 we are working with our supplier on implementing corrective and preventive actions.

If the particulate goes undetected and solution is administered, the particle may potentially block the infusion of the solution to the patient, resulting in a delay in therapy. Iron particulate may put a patient at risk from MRI (strong magnetic field exposure) as metal particulate, could potentially dislodge and be pulled through tissue causing inflammation and tissue trauma. The administration of an injectable with the presence of foreign particulates may potentially cause thrombophlebitis, bacteremia, sepsis, and/or endocarditis and death may result. Signs and symptoms could include redness, pain, swelling at the site, fever, shortness of breath, tachycardia, nausea, and vomiting.

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Anyone with an existing inventory should immediately stop use and quarantine any affected product and return the product to Stericycle. For additional assistance, call Stericycle at 1-866-891-1984 between 8 a.m. and 5 p.m., ET, Monday through Friday.

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

Any adverse reactions or quality problems experienced with the use of this product may be reported to the U.S. Food and Drug Administration's (FDA) MedWatch Adverse Events Program either online, by regular mail or by fax.

- **Online:** www.fda.gov/medwatch/report.htm¹
- **Regular mail:** use postage-paid, pre-addressed Form FDA3500 available at www.fda.gov/MedWatch/getforms.htm²
- **Fax:** 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. 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 16,000 employees. Learn more at www.hospira.com³.

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