Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 4, 2013

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

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

SUBJECT: Hospira Inc Recall [Drug]

AFFECTED PRODUCT: **Metoclopramide Injection and Ondansetron Injection Due to Glass Particulate Matter (glass strands) Affixed to the Inside of the Vial Walls**

SUMMARY: **Unclassified Recall; Hospira, Inc. (NYSE: HSP), announced today it initiated a voluntary nationwide recall of one lot of Metoclopramide Injection, USP, 10 mg/2 mL (5 mg/mL), NDC 0409-3414-01, Lot 28-104-DK and two lots of Ondansetron Injection, USP, 4 mg/2 mL, (2 mg/mL), NDC 0409-4755-03, Lots 29-484-DK and 29-510-DK. This action is due to a confirmed vial defect where glass particulate matter (glass strands) were identified as being affixed to the inside of the vial walls. There is potential for the glass particulates to dislodge into the solution. The administration of an injectable with the presence of foreign particulates may potentially result in local inflammation, thrombophlebitis, and/or low-level allergic response. Signs and symptoms could include redness, pain, swelling at the site, fever, shortness of breath, tachycardia, nausea and vomiting. Additionally, the particulate contaminants could potentially act as an emboli and impede blood flow causing tissue/organ damage, especially in vulnerable patients such as those undergoing surgery, immunosuppressed individuals, infants, children and the elderly, as well as patients with micro or macrovascular disease, such as cardiac and renal disease, who may be more at risk since their vasculature, and end organs, are already compromised.**

SUGGESTED ACTION: **The affected lots were distributed nationwide between June 2013 and September 2013 to wholesalers/distributors, hospitals and pharmacies. Recommend notification of affected parties via phone, fax or e-mail. Detailed store information is not available at this time. Anyone with an existing inventory should stop use and distribution, quarantine the product immediately, and call Stericycle at 1-877-497-3125 between the hours of 8am to 5pm ET, Monday through Friday, to arrange for the return of the product. Furthermore, if any recalled products are found, please notify this office at 317-233-3213.**

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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 ISSUES A VOLUNTARY NATIONWIDE RECALL OF ONE LOT OF METOCLOPRAMIDE INJECTION, USP, AND TWO LOTS OF ONDANSETRON INJECTION, USP, DUE TO GLASS (GLASS STRANDS) PARTICULATES CAUSED BY GLASS SUPPLIER DEFECT

Contact:
Consumer:
1-800-615-0187
medcom@hospira.com

Media:
1-224-212-2357

FOR IMMEDIATE RELEASE - October 1, 2013 - Hospira, Inc. (NYSE: HSP), announced today it initiated a voluntary nationwide recall of one lot of Metoclopramide Injection, USP, 10 mg/2 mL (5 mg/mL), NDC 0409-3414-01, Lot 28-104-DK and two lots of Ondansetron Injection, USP, 4 mg/2 mL, (2 mg/mL), NDC 0409-4755-03, Lots 29-484-DK and 29-510-DK. This action is due to a confirmed vial defect where glass particulate matter (glass strands) were identified as being affixed to the inside of the vial walls. There is potential for the glass particulates to dislodge into the solution.

The administration of an injectable with the presence of foreign particulates may potentially result in local inflammation, thrombophlebitis, and/or low-level allergic response. Signs and symptoms could include redness, pain, swelling at the site, fever, shortness of breath, tachycardia, nausea and vomiting. Additionally, the particulate contaminants could potentially act as an emboli and impede blood flow causing tissue/organ damage, especially in vulnerable patients such as those undergoing surgery, immunosuppressed individuals, infants, children and the elderly, as well as patients with micro or macrovascular disease, such as cardiac and renal disease, who may be more at risk since their vasculature, and end organs, are already compromised.

To date, Hospira has not received reports of any adverse events associated with this issue for these lots. This recall is being conducted as a precautionary measure. Hospira advised customers of this recall in a letter dated September 24, 2013. Hospira has completed an investigation where the root cause findings are attributed to a supplier's manufacturing glass defect. As a result of this issue, Hospira is working with its supplier on implementing corrective and preventive actions.

Metoclopramide Injection, USP, 10 mg/2 mL (5 mg/mL), NDC 0409-3414-01, Lot 28-104-DK (the lot number may be followed by a 01), is packaged in a 2 mL single-dose fliptop vial, with an expiration date of October 1, 2014.

Ondansetron Injection, USP, 4 mg/2 mL (2 mg/mL), NDC 0409-4755-03, Lots 29-484-DK and 29-510-DK (the lot numbers may be followed by a 01) are packaged in a 2 mL single-dose fliptop vial, with an expiration date of May 1, 2015.

Both products are packaged as 25 units per carton/100 units per case in glass fliptop vials.

The affected lots were distributed nationwide between June 2013 and September 2013 to wholesalers/distributors, hospitals and pharmacies.

Anyone with an existing inventory should stop use and distribution, quarantine the product immediately, and call Stericycle at 1-877-497-3125 between the hours of 8am to 5pm ET, Monday through Friday, to arrange for the return of the product. Replacement product from other lots is available.

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.htm[1]
- **Regular mail:** use postage-paid, pre-addressed Form FDA3500 available at www.fda.gov/medwatch/report.htm[2]
- **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.com[3] [4].

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