Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: January 6, 2016

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: **MAGNESIUM SULFATE IN WATER FOR INJECTION**

SUMMARY: **Unclassified Recall; The recall is due to an incorrect barcode. The barcode on the overwrap is correct; however, there is potential for the primary container barcode to be mislabeled with the barcode for HEPARIN SODIUM 2000 USP UNITS/1000 mL in 0.9%SODIUM CHLORIDE INJECTION.**

The recalled product is MAGNESIUM SULFATE IN WATER FOR INJECTION (0.325 mEq Mg/mL) 40 mg/mL 2g total, 50 mL (NDC: 0409-6729-24, Lot 53-113-JT, Expiry 1NOV2016). The product is packaged 50 mL fill, in 100 mL container bags and sold 24 bags per carton (NDC: 0409-6729-24, Lot 53-113-JT, Expiry 1NOV2016).**

The lot was distributed nationwide in the U.S. to wholesalers, distributors and hospitals from September 2015 to November 2015.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-877-650-7695 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.**

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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 Magnesium Sulfate in Water for Injection Due to Incorrect Barcode Labeling on the Primary Container

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January 5, 2016

Contact

Consumers

1-888-345-4680

Firm Press Release
View Product Photos

Hospira, Inc., a Pfizer company, has announced a voluntary recall of one lot of, MAGNESIUM SULFATE IN WATER FOR INJECTION (0.325 mEq Mg**/mL) 40 mg/mL 2g total, 50 mL (NDC: 0409-6729-24, Lot 53-113-JT, Expiry 1NOV2016) to the user level due to a confirmed customer report of an incorrect barcode on the primary bag labeling. The product has a barcode identifying the product contents on both the overwrap and on the primary container. The barcode on the overwrap is correct; however, there is potential for the primary container barcode to be mislabeled with the barcode for HEPARIN SODIUM 2000 USP UNITS/1000 mL in 0.9%SODIUM CHLORIDE INJECTION. The product is labeled with the correct printed name on the primary container and overwrap. To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

If the incorrect barcode on Magnesium Sulfate in Water for Injection, is not detected prior to dispensing or administration to a patient, and the product is administered based on the printed name, patient harm is unlikely since the barcode on the overwrap and readable text on the primary container and overwrap are correct. However, if detected, there is the potential for delay in treatment of Magnesium Sulfate in Water for Injection that can result in life-threatening seizures, stroke, cerebral hemorrhage and maternal death, and attendant risks to the fetus, including fetal demise. Administration of the magnesium sulfate drug product to a patient who is prescribed heparin and in whom the Magnesium Sulfate is contraindicated can result in serious adverse events related to the drug's pharmacologic action and may require medical intervention. Although serious in nature, the likelihood of this risk to occur is low due to the high detectability of this nonconformance.

Magnesium Sulfate in Water for Injection is indicated for the prevention and control of seizures in preeclampsia and eclampsia, respectively.

The product is packaged 50 mL fill, in 100 mL container bags and sold 24 bags per carton (NDC: 0409-6729-24, Lot 53-113-JT, Expiry 1NOV2016). The lot was distributed nationwide in the U.S. to wholesalers, distributors and hospitals from September 2015 to November 2015. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Customers should notify all users in their facility. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the consumer level. Hospira will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance, call Stericycle at 1-877-650-7695 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product.

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.

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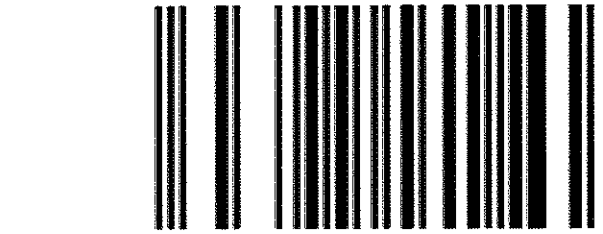
Product Photos


(01)00304096729242

Picture of MAGNESIUM SULFATE IN WATER FOR INJECTION with primary package incorrect barcode circled