Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: March 6, 2015

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 5% Dextrose, Inj., USP**

SUMMARY: **Unclassified Recall; The recall is due to confirmed customer reports of an incorrect barcode on the primary bag labeling. 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 Inj. The product is labeled with the correct printed name on the primary container and overwrap.**

The product is packaged in 50/100 mL container bags and sold 24 bags per carton (NDC: 0409-6727-23, Lot 42-120-JT, Expiry 1DEC2015).

The lot was distributed nationwide in the U.S. to wholesalers, distributors and hospitals from October 2014 to January 2015.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-866-382-9260 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 5% Dextrose Injection Due to Incorrect Barcode Labeling

Contact:
Consumer:
1-888-345-4680

Media:
224-212-2357

FOR IMMEDIATE RELEASE — March 6, 2015 — LAKE FOREST, Ill. — Hospira, Inc., (NYSE: HSP) has announced a voluntary recall of one lot of Magnesium Sulfate in 5% Dextrose, Inj., USP, 10 mg/mL (NDC: 0409-

6727-23, Lot 42-120-JT, Expiry 1DEC2015) to the user level due to confirmed customer reports of an incorrect barcode on the primary bag labeling. 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 Inj. The product is labeled with the correct printed name on the primary container and overwrap.

If the incorrect barcode on Magnesium Sulfate in 5% Dextrose, Inj., USP, 10 mg/ mL 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 5% dextrose, 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. To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

Magnesium sulfate in 5% dextrose injection, USP, is a prescription product administered intravenously for the prevention and control of seizures in preeclampsia and eclampsia, respectively. The product is packaged in 50/100 mL container bags and sold 24 bags per carton (NDC: 0409-6727-23, Lot 42-120-JT, Expiry 1DEC2015). The lot was distributed nationwide in the U.S. to wholesalers, distributers and hospitals from October 2014 to January 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 1-866-382-9260 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

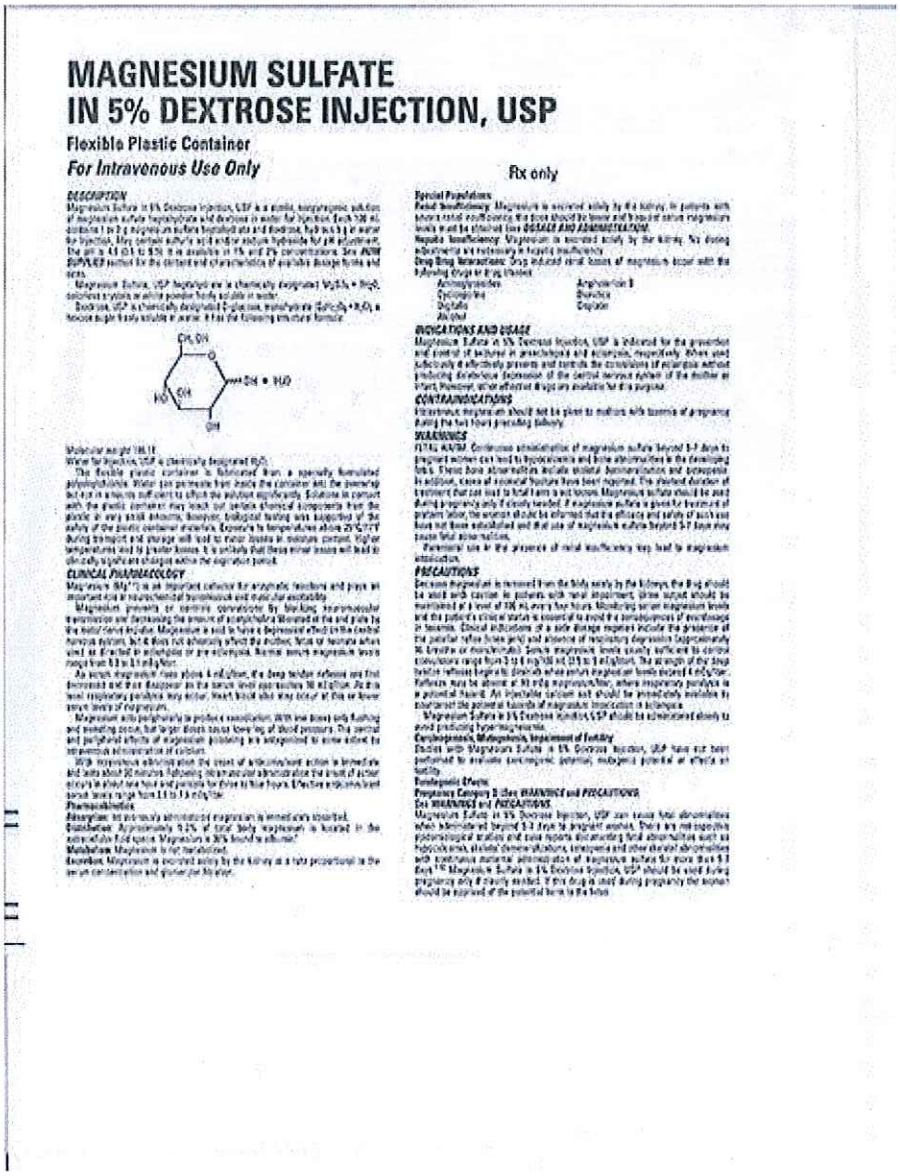
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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. Learn more at www.hospira.com.

Hospira Issues a Voluntary Nationwide Recall of One Lot of Magnesium Sulfate in 5% Dextrose Injection Due to Incorrect Barcode Labeling

Photo



MAGNESIUM SULFATE
IN 5% DEXTROSE INJECTION, USP

Flexible Plastic Container

For Intravenous Use Only

Rx only

DESCRIPTION

INDICATIONS AND USAGE

CONTRAINDICATIONS

WARNINGS

PRECAUTIONS

CLINICAL PHARMACOLOGY

[illegible]

Labor and Delivery

[illegible]

Nursing Mothers

[illegible]

ADVERSE REACTIONS

[illegible]

OVERDOSAGE

[illegible]

For Treatment of Overdose

[illegible]

[illegible]

DOSAGE AND ADMINISTRATION

[illegible]

In Eclampsia

[illegible]

HOW SUPPLIED

Magnesium Sulfate in 5% Dextrose Injection, USP is supplied in single-dose flexible plastic containers as follows:

NDC No.	Size Container	Total Magnesium Sulfate*	Total Magnesium Ion	Magnesium Sulfate* Concentration	Magnesium Ion Concentration	Osmolarity (calc.)
[illegible]	100 mL	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	500 mL	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	1000 mL	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

*As the heptahydrate.

WARNING: DO NOT USE FLEXIBLE CONTAINER IN SERIES CONNECTIONS.

[illegible]

REFERENCES

[illegible]

Revised: [illegible]

Hospira, Inc., Lake Forest, IL 60045 USA [illegible]

Hospira

100 mL NDC 0409-6727-23

MAGNESIUM SULFATE

IN 5% DEXTROSE INJECTION, USP

(0.081 mEq Mg^{++}/mL) 10 mg/mL

1 g TOTAL

EACH 100 mL CONTAINS MAGNESIUM SULFATE HEPTAHYDRATE 1 g (EQUIVALENT TO 8.1 mEq MAGNESIUM) AND DEXTROSE, HYDROUS 5 g IN WATER FOR INJECTION. MAY CONTAIN SULFURIC ACID AND/OR SODIUM HYDROXIDE FOR pH ADJUSTMENT.

pH 4.5 (3.5 to 6.5) 333 mOsmol/LITER (CALC.)

SINGLE-DOSE CONTAINER. DISCARD UNUSED PORTION. FOR I.V. USE. USUAL DOSAGE: SEE INSERT. STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

Rx ONLY

~~LATEX~~

3 V CONTAINS DEHP

Hospira

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HOSPIRA, INC., LAKE FOREST, IL 60045 USA


TO OPEN – TEAR AT NOTCH
100 mL
NDC 0409-6727-23
MAGNESIUM SULFATE
IN 5% DEXTROSE INJECTION, USP
(0.081 mEq Mg++/mL) 10 mg/mL
1g TOTAL
(01) 0 300409 672723 1
Each 100 mL contains magnesium sulfate heptahydrate 1 g (equivalent to 8.1 mEq magnesium) and dextrose, hydrous 5 g in water for injection. May contain sulfuric acid and/or sodium hydroxide for pH adjustment.
333 mOsmol/Liter (CALC.)
pH 4.5 (3.5 to 6.5)
DO NOT ADD SUPPLEMENTARY MEDICATION. WHENEVER POSSIBLE USE CENTRAL ROUTE.
Single-dose container. For I.V. use. Usual dosage: See insert. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections.
The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See insert.
℞ ONLY
LATEX
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OTHER
Printed in USA
F WR-0249 (7/07)
Hospira, Inc., Lake Forest, IL 60045 USA
Hospira
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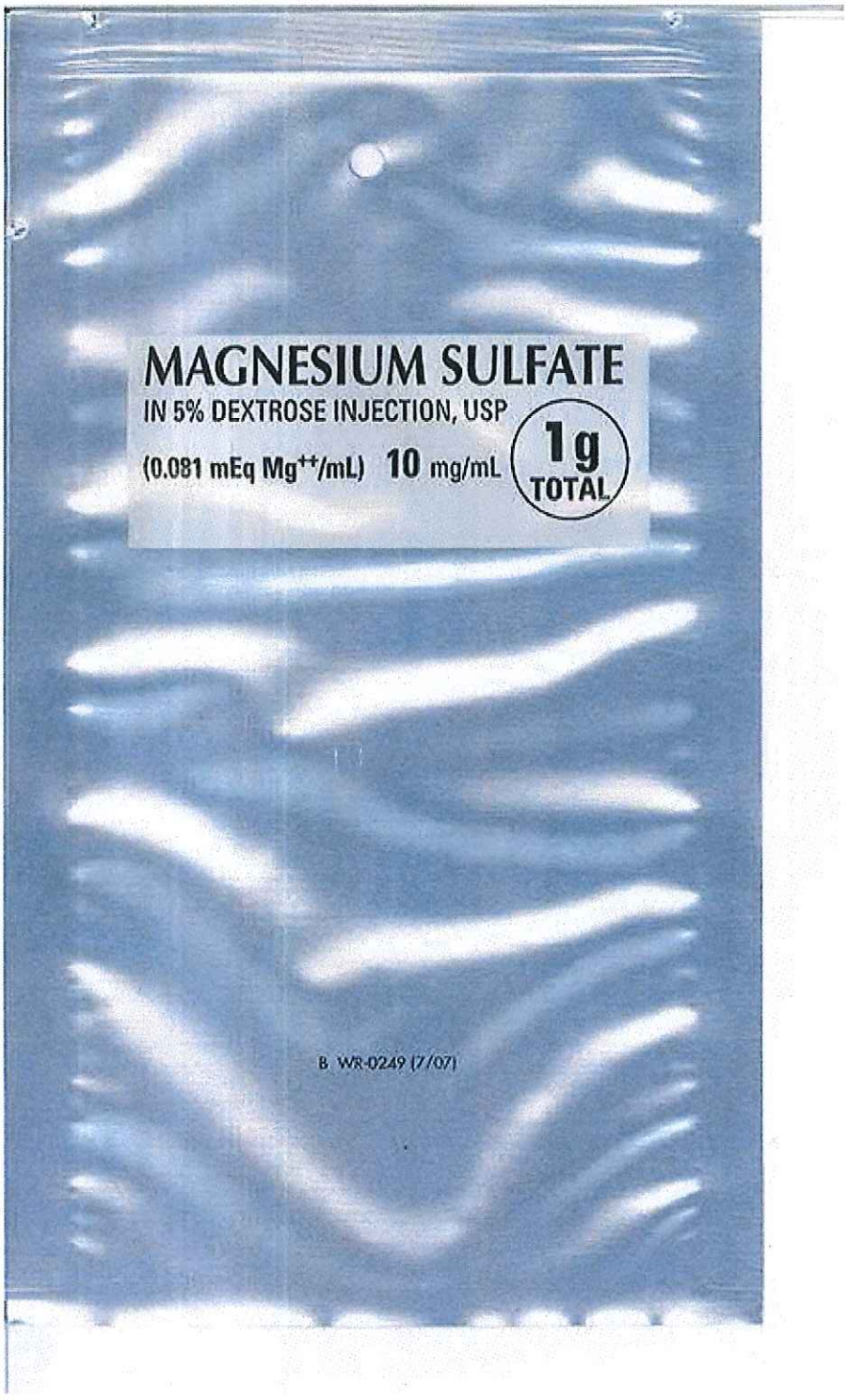
MAGNESIUM SULFATE
IN 5% DEXTROSE INJECTION, USP
(0.081 mEq Mg^{++}/mL) 10 mg/mL
1g
TOTAL
B WR-0249 (7/07)