



**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**

Consumers:
1-888-345-4680

Media:
610-329-1340

LAKE FOREST, Ill., Jan. 05, 2016 -- 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.

Hospira, Inc., a Pfizer company
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com

#####

RED

50 mL

NDC 0409-6729-24

MAGNESIUM SULFATE

IN WATER FOR INJECTION

2g
TOTAL

(0.325 mEq Mg⁺⁺/mL) **40** mg/mL

BLUE

EACH 50 mL CONTAINS MAGNESIUM SULFATE HEPTAHYDRATE 2 g (EQUIVALENT TO 16.25 mEq MAGNESIUM) IN WATER FOR INJECTION. MAY CONTAIN SULFURIC ACID AND/OR SODIUM HYDROXIDE FOR pH ADJUSTMENT.

pH 4.5 (3.5 to 6.5) 325 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



CONTAINS DEHP



PRINTED IN USA IM-1532 (6/07)
HOSPIRA, INC., LAKE FOREST, IL 60045 USA

Packaging Graphics Art

List	6729
Commodity	IM-1532v2
CR	07-2338
Editor	VS
Date	8/6/07
Artist	AS/TG

Color



THERMAL TRANSFER
Process
Page 1 of 2

APPROVED
By V.Stingle at 11:06 am, Aug 11, 2007



(01)00304096729242

**Packaging
Graphics Art**

List 6729
Commodity IM-1532v2
CR 07-2338
Editor VS
Date 8/6/07
Artist AS/TG

**THERMAL TRANSFER
Process
Page 2 of 2**

NOT A VISUAL
REPRESENTATION! FOR
PLANT SCANNING AND
HUMAN READABLE
COMPARISON ONLY.

MAGNESIUM SULFATE IN WATER FOR INJECTION (0.325 mEq Mg**/mL) 40 mg/mL 2g total, 50 mL label and barcode.

EXP. 1 NOV 2016

LOT 53-113-37

NDC 0409-0729-04

50 mL

MAGNESIUM SULFATE

IN WATER FOR INJECTION

2g
TOTAL

(0.325 mEq Mg⁺⁺/mL) 40 mg/mL



EACH 50 mL CONTAINS MAGNESIUM SULFATE HEPTAHYDRATE 2 g (EQUIVALENT TO 16.25 mg MAGNESIUM) IN WATER FOR INJECTION. MAY CONTAIN SULFURIC ACID AND/OR SODIUM HYDROXIDE FOR pH ADJUSTMENT.

pH 4.5 (3.5 to 6.5) 325 mOsmo/LITER (CALCULATED)
SINGLE-DOSE CONTAINER. DISCARD UNUSUED PORTION. FOR I.V. USE. USUAL DOSAGE: 10-20 mL. INSERT, STERILE, NONPYROGENIC. USE OF SOLUTION IS CLEAR AND CONTAINS NO PARTICLES UNDATED. MUST NOT BE USED IN SPINAL CONNECTIONS.

Rx ONLY



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

PRINTED IN USA (M-1532 (6/07))
HOSPIRA, INC., LAKE FOREST, IL 60045 USA