**Hospira Issues A Voluntary Recall For One Lot Of 50% Magnesium Sulfate Injection, USP Due To The Presence Of Particulate**

Consumers Contact: 1-888-345-4680
Media Contact: 610-329-1340

LAKE FOREST, Ill., April 13, 2016 - Hospira, Inc., a Pfizer company, is voluntarily recalling one lot of 50% Magnesium Sulfate Injection, USP, 10 g/20 mL (0.5 g/ml), 20 mL Single-dose vials, Lot 50-343-DK, Expiration 01FEB2017, NDC 0409-2168-02, to the hospital level due to a confirmed customer complaint for the presence of particulate matter, within one single-dose fliptop vial. A recall was previously executed for this lot on March 23, 2016 due to a confirmed high out of specification (OOS) result for pH.

If the particulate is detected prior to dispensing or administration to a patient, patient harm is unlikely. If the delay of therapy is prolonged, there is the potential for serious medical consequences for mother and fetus requiring medical intervention. If the particulate is not observed prior to administration, it may result in localized swelling, redness, pain at the site of administration or veins, allergic reactions to the foreign particle, microembolic effects as well as possible fetal harm. The likelihood of serious patient harm is considered low due to high-detectability of this non-conformance.

To date, Hospira has not received reports of any adverse events associated with this issue for this lot. Hospira places the

utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process.

The product is packaged 1 box of 25 units (1x25)/case pack 4 boxes of 25 units (4x25). The lot was distributed from March 2015 through June 2015 in the United States.

Magnesium Sulfate Injection, USP is suitable for replacement therapy in magnesium deficiency, especially in acute hypomagnesemia accompanied by signs of tetany similar to those observed in hypocalcemia. In such cases, the serum magnesium (Mg++ ) level is usually below the lower limit of normal (1.5 to 2.5 or 3.0 mEq/liter) and the serum calcium (Ca++ ) level is normal (4.3 to 5.3 mEq/liter) or elevated.

In total parenteral nutrition, magnesium sulfate may be added to the nutrient admixture to correct or prevent hypomagnesemia which can arise during the course of therapy.

Magnesium Sulfate injection is also indicated for the prevention and control of seizure in pre-eclampsia and eclampsia.

Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Inform health care professionals in your organization of this recall. If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Further, please instruct entities that may have received the recalled product from you that if they redistributed the product, they should notify their accounts, locations or facilities of the recall to the hospital 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 1-866-201-9068 between the hours of 8 a.m. to 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 |

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 executed with the knowledge of the U.S. Food and Drug Administration.

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**Product Name:** 50% Magnesium Sulfate Injection, USP, 10 g /20 mL (0.5 g/mL), 20 mL Single-use