Hospira Issues A Voluntary Recall For One Lot Of Sodium Bicarbonate Injection, USP Due To The Presence Of A Particulate

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

LAKE FOREST, Ill., March 18, 2016 - Hospira, Inc., a Pfizer company, is voluntarily recalling one lot of 8.4% Sodium Bicarbonate Injection, USP (NDC: 0409-6625-02, Lot 56-148-EV, Expiry 1AUG2017) at the hospital/retail level due to the presence of a particulate within a single-dose glass fliptop vial. The issue was identified through a confirmed complaint.

If the particulate is not observed prior to IV administration and breaks off into smaller particulates, passing through the catheter, it may result in localized inflammation, allergic reaction, including anaphylaxis, granuloma formation or microembolic effects (IV only). Larger particulates may block the infusion of solution, potentially resulting in a delay in therapy. The likelihood of risk to the patient is low due to the high detectability of the particulate prior to or at the point of care. Although serious in nature, the probability of harm in this case is low due to the high detectability of the 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 50 mEq (1mEq/mL), 4.2 grams (84 mg/mL), 50mL, Single-dose, packaged 4 boxes of 25 vials per case. The lot was distributed nationwide in the U.S. to wholesalers and hospitals in December 2015. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Sodium Bicarbonate Injection, USP is indicated in the treatment of metabolic acidosis; in the treatment of certain drug intoxications, in poisoning by salicylates or methyl alcohol and in certain hemolytic reactions. Sodium bicarbonate also is indicated in severe diarrhea, which is often accompanied by significant loss of bicarbonate.

Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Inform Healthcare 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/retail 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 1-888-965-6077 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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