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Pharmacy Safety Alert

June 15, 2017

Hospira Issues a Voluntary Nationwide Recall For 8.4% Sodium Bicarbonate Injection, USP, Neut tm (Sodium Bicarbonate 4% Additive Solution), QUELICIN tm (Succinylcholine Chloride Injection, USP) and Potassium Phosphates Injection, USP Due To a Potential For Lack Of Sterility Assurance

Hospira, Inc., a Pfizer company, is voluntarily recalling 42 lots of 8.4% Sodium Bicarbonate Injection, USP, 50 mL vials, 5 lots of NeutTM (Sodium Bicarbonate 4% additive solution) 5 mL vials, 5 lots of QUELICINTM (Succinylcholine Chloride Injection, USP) 200 mg/10 mL vials and 7 lots of Potassium Phosphates Injection, USP, 45 mM vials to the hospital/retail level due to microbial growth detected during a routine simulation of the manufacturing process, which represents the potential introduction of microorganisms into the products.

In the event that impacted product is administered to a patient, there is a reasonable probability that the patient may experience adverse events ranging from fever, chills and malaise, to severe adverse events including systemic invasive mycoses or systemic bacterial sepsis. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated. No batches of distributed product have been identified as actually containing microorganisms. To date, Hospira has not received reports of any adverse events associated with this issue. Hospira places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process.

QuelicinTM (Succinylcholine Chloride Injection, USP) is indicated as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation; and Potassium Phosphates Injection, USP 3 mM P/mL (millimoles/mL) is indicated as a source of phosphorus, for addition to large volume intravenous fluids, to prevent or correct hypophosphatemia in patients with restricted or no oral intake. It is also useful as an additive for preparing specific intravenous fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions.

See Appendix for lots and packaging information.

These lots were distributed nationwide in the U.S. (including Puerto Rico), Dutch Antilles, Barbados, Canada, Philippines, Kuwait, and Singapore to wholesalers and hospitals from January to June 2017. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Pfizer is working diligently to restore supply of these products and is in communication with the FDA to address any supply issues.

Anyone with an existing inventory of the recalled lots should stop use and distribution and quarantine 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 1-800-805-3093 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
Pfizer Complaint Management	1-800-438-1985 (24 hours a day 7 days per week)	To report adverse events or product complaints
Pfizer Medical Information	1-800-615-0187 (8am to 7pm EST Monday through Friday)	Medical inquiries

Adverse reactions or quality problems experienced with the use of these products 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.htmor 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.

Appendix: Lots and Packaging Information

8.4% Sodium Bicarbonate Inj., USP

NDC	Lot Numbers	Expiration Date	Strength	Configuration/Count
0409-6625-02	72109EV	12/01/2018	8.40% 50ml	1X25 VL
72110EV	12/01/2018	8.40%	50ml	1X25 VL
72112EV	12/01/2018	8.40%	50ml	1X25 VL
72113EV	12/01/2018	8.40%	50ml	1X25 VL
72114EV	12/01/2018	8.40%	50ml	1X25 VL
72120EV	12/01/2018	8.40%	50ml	1X25 VL
73068EV	01/01/2019	8.40%	50ml	1X25 VL
73071EV	01/01/2019	8.40%	50ml	1X25 VL
73072EV	01/01/2019	8.40%	50ml	1X25 VL
73224EV	01/01/2019	8.40%	50ml	1X25 VL
73225EV	01/01/2019	8.40%	50ml	1X25 VL
73230EV	01/01/2019	8.40%	50ml	1X25 VL

NDC	Lot Numbers	Expiration Date	Strength	Configuration/Count
73231EV	01/01/2019	8.40%	50ml	1X25 VL
73232EV	01/01/2019	8.40%	50ml	1X25 VL
73233EV	01/01/2019	8.40%	50ml	1X25 VL
73234EV	01/01/2019	8.40%	50ml	1X25 VL
73235EV	01/01/2019	8.40%	50ml	1X25 VL
73236EV	01/01/2019	8.40%	50ml	1X25 VL
73298EV	01/01/2019	8.40%	50ml	1X25 VL
74058EV	02/01/2019	8.40%	50ml	1X25 VL
74104EV	02/01/2019	8.40%	50ml	1X25 VL
74105EV	02/01/2019	8.40%	50ml	1X25 VL
74106EV	02/01/2019	8.40%	50ml	1X25 VL
74107EV	02/01/2019	8.40%	50ml	1X25 VL
74197EV	02/01/2019	8.40%	50ml	1X25 VL
74198EV	02/01/2019	8.40%	50ml	1X25 VL

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NDC	Lot Numbers	Expiration Date	Strength	Configuration/Count
74199EV	02/01/2019	8.40%	50ml	1X25 VL
74200EV	02/01/2019	8.40%	50ml	1X25 VL
74201EV	02/01/2019	8.40%	50ml	1X25 VL
75171EV	03/01/2019	8.40%	50ml	1X25 VL
75172EV	03/01/2019	8.40%	50ml	1X25 VL
75173EV	03/01/2019	8.40%	50ml	1X25 VL
75174EV	03/01/2019	8.40%	50ml	1X25 VL
75175EV	03/01/2019	8.40%	50ml	1X25 VL
75176EV	03/01/2019	8.40%	50ml	1X25 VL
75177EV	03/01/2019	8.40%	50ml	1X25 VL
75178EV	03/01/2019	8.40%	50ml	1X25 VL
75293EV	03/01/2019	8.40%	50ml	1X25 VL
75418EV	03/01/2019	8.40%	50ml	1X25 VL
75419EV	03/01/2019	8.40%	50ml	1X25 VL

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Neut™ Sodium Bicarbonate additive solution 4%

NDC	Lot Numbers	Expiration Date	Strength	Configuration/Count
0409-6609-25	75386EV	03/1/2019	4%/5ML	1X25 FTV NOVA PLUS
0409-6609-02	72226EV	12/01/2018	4%/5ML	1X25 FTV
0409-6609-02	72236EV	12/01/2018	4%/5ML	1X25 FTV
0409-6609-02	75382EV	03/01/2019	4%/5ML	1X25 FTV
0409-6609-02	75383EV	03/01/2019	4%/5ML	1X25 FTV

Succinylcholine Chloride Injection, USP/Quelicin®

NDC	Lot Numbers	Expiration Date	Strength	Configuration/Count
0409-6629-02	74393EV	05/01/2018	200mg/10ml	1X25 FTV
0409-6629-02	75157EV 75367EV	06/01/2018 06/01/2018	200mg/10ml	1X25 FTV
0409-6629-25	75158EV	06/01/2018	200mg/10ml	1X25 FTV NOVA PLUS
0409-6629-02	75367EV	06/01/2018	200mg/10ml	1X25 FTV

Potassium Phosphates Injection, USP

NDC	Lot Numbers	Expiration Date	Strength	Configuration/Count
0409-7295-01	74119EV	02/01/2019	45mM	25X15ML
0409-7295-01	74120EV	02/01/2019	45mM	25X15ML
0409-7295-01	74121EV	02/01/2019	45mM	25X15ML
0409-7295-01	74307EV	02/01/2019	45mM	25X15ML
0409-7295-01	74326EV	03/01/2019	45mM	25X15ML
0409-7295-01	74327EV	03/01/2019	45mM	25X15ML
0409-7295-01	75215EV	03/01/2019	45mM	25X15ML