Important Safety Information on Type I Recall
Sodium Bicarbonate Inj 8.4%
50 mL vials –Risk of Infection Due to Potential Microbial Contamination

Hospira
A Pfizer Company

2017/06/30

Audience
Healthcare professionals including cardiologists, nephrologists, surgeons, internists, pharmacists, pharmacy technicians, nurses and emergency room staff.

Key messages

- **Two lots of Sodium Bicarbonate Injection 8.4%, 50 mL vials manufactured for Hospira Healthcare Corporation have potentially been exposed to two fungal organisms (*Penicillium chrysogenum* and *Doratomyces asperulus*) and a single bacterial organism (*Actinomadura oligospora)*.**
- **Despite the low likelihood of patients being exposed to potentially contaminated product, a type I voluntary recall was initiated for the two impacted lots, as a precaution.**
- **The microorganisms were detected during a routine simulation exercise of normal manufacturing operations without using the actual drug. However, microbial growth or loss of sterility has not been identified in Sodium Bicarbonate Injection 8.4%.**
- **Healthcare professionals are advised to:**
  - **Closely monitor the patients that received the potentially impacted products for symptoms and signs of an infection.**
  - **Seek advice regarding appropriate therapy from an infectious disease specialist experienced in fungal and bacterial infections treatment if impacted patients develop infection or sepsis signs or symptoms.**

What is the issue?
Two lots of Sodium Bicarbonate Inj 8.4%, 50 mL vials, have potentially been exposed to two fungal organisms (*Penicillium chrysogenum* and *Doratomyces asperulus*) and a single bacterial organism (*Actinomadura oligospora*). Although no microbial growth or loss of sterility has been identified in Sodium Bicarbonate Inj 8.4% lots, there is a possibility of breach in their sterility assurance. Despite the

low likelihood of patients being exposed to potentially contaminated product, a type I voluntary recall was initiated for the two impacted lots, as a precaution.

If you have any inventory of the impacted lot, please stop use immediately. Please conduct an assessment of inventory and immediately send the completed product recall return form (provided with the recall notification letter) by fax to 1-800-420-2019, even if you do not have any recalled stock-on hand. In this case, check the box to this effect on the form. Your response is vital to Pfizer Canada's ability to monitor the effectiveness of this voluntary recall. Your immediate attention to the above instructions is required. If not already done, please return the form immediately, even if you do not have recalled stock on-hand. Return affected product to Med-Turn International Inc (Inmar Healthcare Network) using the instructions provided with the customer letter.

Products affected

PRODUCT DESCRIPTION	DIN	SIZE	Product Code	UPC CODE	LOT #
Sodium Bicarbonate Inj 8.4%	00261998	25 x 50 mL	06625050	Box 25 x 50 mL 18821356625001 Vial 08821356625004	72119EV 72120EV

Background information

Sodium Bicarbonate Inj 8.4% is indicated in the treatment of:

- Metabolic acidosis which may occur in severe renal disease, uncontrolled diabetes, circulatory insufficiency due to shock or severe dehydration, extracorporeal circulation of blood, cardiac arrest, severe primary lactic acidosis and other conditions requiring systemic alkalinisation.
- Certain drug intoxications, including barbiturates, salicylates, methyl alcohol and in hemolytic reactions requiring alkalinization of the urine to diminish nephrotoxicity of blood pigments.
- Severe diarrhea which is often accompanied by a significant loss of bicarbonate.

During a routine simulation of the manufacturing process, a microbial growth was detected, representing a potential introduction of microorganisms into the finished product. It was determined that two lots of Sodium Bicarbonate Inj 8.4%, 50 mL vials, were potentially exposed to two fungal organisms (*Penicillium chrysogenum* and *Doratomyces asperulus*) and a single bacterial organism (*Actinomadura oligospora*). Although the likelihood of patients being exposed to potentially contaminated product was very low, the two lots of the product in vial format were recalled on June 14, 2017 (http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2017/63650r-eng.php#reason-motif).

Information for consumers

Sodium Bicarbonate Inj 8.4% is used to treat a wide range of conditions including metabolic acidosis (build-up of acid in the blood) during open heart surgery, in cases of organ failure, or in some types of cancer chemotherapy. Sodium

Bicarbonate Inj 8.4% is also used as an antidote to certain poisons or to treat diarrhea. The product is administered by health care professionals, usually in a hospital or home care setting.

During the manufacturing process of Sodium Bicarbonate Inj 8.4%, a few lots were potentially in contact with microorganisms. When injected into the body, this could potentially lead to infections causing fever, chills and malaise. Healthcare professionals will take extra precautions and monitor patients when giving the medication.

Information for healthcare professionals

All patients being administered potentially affected Sodium Bicarbonate Inj 8.4% lots should be monitored closely for potential adverse reactions ranging from fever, chills and malaise, to severe adverse reactions including systemic invasive mycoses or systemic bacterial sepsis. The signs and symptoms of these severe adverse reactions such as sepsis are generally nonspecific as they may include (but are not limited to): low blood pressure, fever or hypothermia, chills, rapid breathing, rapid heart rate, confusion/altered mental status, warm skin, reduced urine output, and gastrointestinal symptoms. In addition other signs/symptoms may be more specific depending on the infectious source (e.g. cough, difficulty breathing which may suggest pneumonia, etc.)[1].

If a patient who received potentially impacted product develops signs or symptoms of infection or sepsis, healthcare professionals are advised to consult an infectious disease specialist or other medical practitioner experienced in the management of fungal and bacterial infections regarding appropriate therapy.

Action taken by Health Canada

Health Canada is communicating this important safety information to healthcare professionals via the Recalls and Safety Alerts Database on the Healthy Canadians Web Site. This communication will be further distributed through the MedEffect e-Notice email notification system.

Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any case of potential infection or other serious or unexpected side effects in patients receiving Sodium Bicarbonate Inj 8.4 % in the 50 mL vial should be reported to Pfizer or Health Canada.

Hospira Healthcare Corporation, a Pfizer Company
17300 Trans-Canada Highway
Kirkland, QC
H9J 2M5
Telephone: 1-866-723-7111
Fax: 1-855-242-5652

To correct your mailing address or fax number, contact Pfizer Canada Inc.

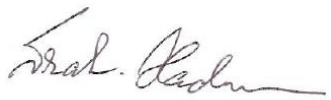
You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Regulatory Operations and Regions Branch
E-mail: dcviu_uvcem@hc-sc.gc.ca
Telephone: 1-800-267-9675
Fax: 1-613-946-5636

Sincerely,



Vratislav Hadrava M.D., Ph.D.
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Pfizer Canada Inc.

[1] R. Neviere – Sepsis syndromes in adults: Epidemiology, definitions, clinical presentation, diagnosis, and prognosis. UpToDate®, version April 26th, 2017 https://www.uptodate.com/contents/sepsis-syndromes-in-adults-epidemiology-definitions-clinical-presentation-diagnosis-and-prognosis