Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Hospira, Inc. Issues a Voluntary Nationwide Recall of 8.4% Sodium Bicarbonate Injection, USP Due to the Presence of Particulate Matter

For Immediate Release

March 15, 2019

Contact

Pfizer Medical Information

800-438-1985, option 3
Medical inquiries

Pfizer Safety

800-438-1985, option 1
To report adverse events or product complaints

Announcement

Hospira, Inc., a Pfizer company, is voluntarily recalling lot numbers 79-238-EV, 79-240-EV and 80-088-EV, NDC# 0409-6625-02, of 8.4% Sodium Bicarbonate Injection USP, 50 mEq/50 mL (1 mEq/mL), to the Hospital/Institution level. The recall was initiated due to the presence of particulate matter, confirmed as glass.

The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening if a critical organ is affected. To date, Hospira, Inc. has not received reports

of any adverse events associated with this issue for these lots. The risk is reduced by the possibility of detection, as the label contains a clear statement directing the healthcare professional to visually inspect the product for particulate matter and discoloration prior to administration.

The 8.4% Sodium Bicarbonate Injection, USP, is a sterile, hypertonic solution of sodium bicarbonate ($NaHCO_3$) in water for administration by the intravenous route. It is indicated for the treatment of metabolic acidosis which may occur in severe renal disease, uncontrolled diabetes, dehydration, severe diarrhea, circulatory insufficiency due to shock, cardiac arrest and severe lactic acidosis. Sodium bicarbonate is also indicated for the treatment of certain drug intoxications.

8.4% Sodium Bicarbonate Injection, USP, NDC# 0409-6625-02, is packaged in 50 mL glass fliptop vials in a case pack of 4 x 25- 50mL. The affected lots and their expiry dates are indicated in the table below. Product was distributed Nationwide to Wholesalers/Distributors/Hospitals in the United States and Puerto Rico from August 2017 to September 2017.

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0409-6625-02	79-238-EV	1JUL2019	50 mEq/50 mL	Case Pack 4 x 25, 50mL
0409-6625-02	79-240-EV	1JUL2019	50 mEq/50 mL	Case Pack 4 x 25, 50mL
0409-6625-02	80-088-EV	1AUG2019	50 mEq/50 mL	Case Pack 4 x 25, 50mL

Hospira, Inc. places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process. Hospira, Inc. has notified its direct customers via a recall letter to arrange for return of any recalled product.

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. 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/Pfizer using the below information.

Contact	Contact Information	Areas of Support
Pfizer Medical Information	1-800-438-1985, option 3 (8am to 7pm ET Monday through Friday)	Medical inquiries
Pfizer Safety	1-800-438-1985, option 1 (24 hours a day, 7 days per week)	To report adverse events or product complaints

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 (http://www.fda.gov/medwatch/report.htm)**
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://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.

###

Follow FDA

- **Follow @US_FDA (https://twitter.com/US_FDA) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **Follow FDA (https://www.facebook.com/FDA) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **Follow @FDArecalls (https://twitter.com/fdarecalls) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **Recent Recalled Product Photos on FDA's Flickr Photostream (https://www.flickr.com/photos/fdaphotos/sets/72157663245186459/) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

More in Recalls, Market Withdrawals, & Safety Alerts (/Safety/Recalls/default.htm)

Archive for Recalls, Market Withdrawals & Safety Alerts (/Safety/Recalls/ArchiveRecalls/default.htm)

Enforcement Reports (/Safety/Recalls/EnforcementReports/default.htm)

Industry Guidance (/Safety/Recalls/IndustryGuidance/default.htm)

Major Product Recalls (/Safety/Recalls/MajorProductRecalls/default.htm)