Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: January 27, 2016

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Baxter International Inc. - RECALL [Drug]

AFFECTED PRODUCT: Intravenous (IV) solutions

SUMMARY: Unclassified Recall; The recall is due to the potential for leaking containers and particulate matter.

The recalls affect the following products and lots:

Product Code	Product Description	Lot Number	Expiration Date	NDC
2B0043	0.9% Sodium Chloride Injection, USP, 100mL in Mini-Bag Plus Container	P337857	07/31/2016	0338-0553-18
2B0043	0.9% Sodium Chloride Injection, USP, 100mL in Mini-Bag Plus Container	P328997	01/31/2016	0338-0553-18
2B3421	Metronidazole Injection, USP 500mg/100mL	P339135	08/31/2017	0338-1055-48
2B7721	Clinimix E 5/15 (5% AA w/Electrolytes in 15% Dextrose w/Calcium)	P333930	05/31/2017	0338-1123-04

The recalled products were distributed nationwide.

SUGGESTED ACTION: For consumer inquiry only. Consumers with questions regarding this recall can call Baxter at 1-800-422-9837, Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m. Central Time, or e-mail Baxter at onebaxter@baxter.com.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Baxter initiates Voluntary Nationwide Recall of Select Lots of IV Solutions Due to the Potential for Leaking Containers and Particulate Matter

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

For Immediate Release

January 26, 2016

Contact

Consumers

Baxter
onebaxter@baxter.com
1-800-422-9837

Firm Press Release

View Product Photos

Baxter International Inc. announced today it is voluntarily recalling four lots of intravenous (IV) solutions to the hospital/user level due to the potential for leaking containers and particulate matter. Baxter was made aware of these issues as the result of two complaints for leaking containers and one customer complaint each for three lots due to particulate matter. In each case, the issue was discovered prior to patient administration and there have been no adverse events associated with these incidents reported to Baxter to date.

Leaking containers could result in contamination of the solution. If not detected, this could lead to a bloodstream infection, worsened patient condition or other serious adverse health consequences. Injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack, damage to other organs such as the kidney or liver, or death. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs.

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Leaking containers were confirmed in 11 units of one lot (P337857) of 0.9% Sodium Chloride Injection, USP, 100mL in Mini-Bag Plus Container, and a subsequent investigation identified the root cause as a mechanical issue that affected one machine during a single shift. The mechanical issue has since been remedied.

A single unit in a separate lot (P328997) of 0.9% Sodium Chloride Injection, USP, 100mL in Mini-Bag Plus Container was found to contain a fragment of cardboard particulate matter. A unit from lot P339135 of Metronidazole Injection, USP 500mg/100mL was found to contain cloth fiber particulate matter, and a unit from lot P333930 of Clinimix E 5/15 (5% Amino Acid with Electrolytes in 15% Dextrose with Calcium) was found to contain a small fragment of dried skin particulate matter.

0.9% Sodium Chloride Injection, USP is indicated as a source of water and electrolytes and may also be used as diluent for reconstitution of a powdered drug product packaged in a vial with a 20 mm closure. The lots being recalled were distributed to customers and distributors nationwide between February 22, 2015 and December 28, 2015.

Metronidazole Injection, USP is indicated in the treatment of serious infections caused by susceptible anaerobic bacteria. Indicated surgical procedures should be performed in conjunction with Metronidazole Injection, USP

therapy. In a mixed aerobic and anaerobic infection, antibiotics appropriate for the treatment of the aerobic infection should be used in addition to Metronidazole Injection, USP. Metronidazole Injection, USP has been shown to be effective in Bacteroides fragilis infections resistant to clindamycin, chloramphenicol and penicillin. The lot being recalled was distributed to customers and distributors nationwide between October 9, 2015 and January 18, 2016.

Metronidazole Injection, USP is indicated in the treatment of serious infections caused by susceptible anaerobic bacteria. Indicated surgical procedures should be performed in conjunction with Metronidazole Injection, USP therapy. In a mixed aerobic and anaerobic infection, antibiotics appropriate for the treatment of the aerobic infection should be used in addition to Metronidazole Injection, USP. Metronidazole Injection, USP has been shown to be effective in Bacteroides fragilis infections resistant to clindamycin, chloramphenicol and penicillin. The lot being recalled was distributed to customers and distributors nationwide between October 9, 2015 and January 18, 2016.

Clinimix E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections are indicated as a caloric component in a parenteral nutrition regimen. The product is used as the protein (nitrogen) source for offsetting nitrogen loss or for treatment of negative nitrogen balance in patients where the alimentary tract cannot or should not be used, gastrointestinal absorption of protein is impaired, or metabolic requirements for protein are substantially increased. The lot being recalled was distributed to customers and distributors nationwide between May 29, 2015 and December 3, 2015.

Customers were notified via letter that they should not use product from the recalled lots. Recalled product should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 1-888-229-0001, Monday through Friday, between the hours of 7:00 a.m. and 6:00 p.m., Central Time. Unaffected lots of product are available for replacement.

Consumers with questions regarding this recall can call Baxter at 1-800-422-9837, Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m. Central Time, or e-mail Baxter at onebaxter@baxter.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these drug products.

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

About Baxter

Baxter International Inc. provides a broad portfolio of essential renal and hospital products, including home, acute and in-center dialysis; sterile IV solutions; infusion systems and devices; parenteral nutrition; biosurgery products and anesthetics; and pharmacy automation, software and services. The company's global footprint and the critical nature of its products and services play a key role in expanding access to healthcare in emerging and developed countries. Baxter's employees worldwide are building upon the company's rich heritage of medical breakthroughs to advance the next generation of healthcare innovations that enable patient care.

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Product Photos

LOT EXP

NDC 0338-1055-48

Metronidazole

Metronidazole Injection USP

500 mg per 100 mL
(5 mg / mL)

100 mL STERILE SINGLE DOSE CONTAINER EACH 100 mL CONTAINS 500 mg METRONIDAZOLE USP 790 mg SODIUM CHLORIDE USP 47.6 mg DIBASIC SODIUM PHOSPHATE DRIED USP 22.9 mg CITRIC ACID ANHYDROUS USP pH 5.5 (4.5 TO 7.0) OSMOLARITY 310 mOsmol/L (CALC) USUAL DOSAGE *SEE INSERT* **DO NOT ADD SUPPLEMENTARY MEDICATION** STORE IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE OF 59°F TO 86°F (15°C TO 30°C) **RX ONLY**

Baxter

USA 2B3421

LOT EXP

2B0043 NDC 0338-0553-18

0.9% Sodium Chloride Injection USP

MINI-BAG Plus Container

100 mL EACH 100 mL CONTAINS 900 mg SODIUM CHLORIDE USP pH 5.0 (4.5 TO 7.0) mEq/100 mL SODIUM 15 CHLORIDE 15 OSMOLARITY 308 mOsmol/L (CALC) STERILE NONPYROGENIC READ PACKAGE INSERT FOR FULL INFORMATION ADDITIVES MAY BE INCOMPATIBLE DOSAGE INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN CAUTIONS MUST NOT BE USED IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS CLEAR **RX ONLY**

VIAFLEX SINGLE DOSE CONTAINER PL 146 PLASTIC

Baxter

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA