



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: July 31, 2015
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: 0.9 % Sodium Chloride Injection, USP (AUTO-C)

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

This recall affects the following lot:

<u>Product Code</u>	<u>Product Description</u>	<u>Lot Number</u>	<u>Expiration Date</u>	<u>NDC</u>
2B1323N	0.9 % Sodium Chloride Injection, USP (AUTO-C)	C964601	04/30/2016	0338-0049-03

The lot being recalled was distributed to customers and distributors nationwide between January 22, 2015 and February 12, 2015.

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.

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 One Lot Of IV Solution Due To The Potential For Leaking Containers, Particulate Matter And Missing Port

Contact:
Consumer:
1-800-422-9837

Media:
John O'Malley



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To promote and provide
essential public health services.

(224) 948-5353
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FOR IMMEDIATE RELEASE – July 30, 2015 – Deerfield, Illinois – Baxter International Inc. announced today it is voluntarily recalling one lot of intravenous (IV) solution to the hospital/user level due to the potential for leaking containers, particulate matter and missing port protectors. Baxter was made aware of these issues through customer complaints. There have been no adverse events associated with this lot reported to Baxter to date.

Leaking containers, particulate matter and missing port protectors could result in contamination of the solution. If not detected, this could lead to a bloodstream infection 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 or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs.

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0.9 % Sodium Chloride Injection, USP is indicated as a source of water and electrolytes. The lot being recalled was distributed to customers and distributors nationwide between January 22, 2015 and February 12, 2015. Customers were notified via letter that they should not use product from the recalled lot. 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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