Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: November 24, 2014

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: **Highly Concentrated Potassium Chloride Injection, 10 mEq per 100 mL**

SUMMARY: **Unclassified Recall; The recall is due to a complaint of mislabeling of the overpouch. The inability to detect this overpouch mislabeling at the point of care may result in the administration of a dose lower than intended. In the high-risk patient population – patients prone to severe electrolyte imbalance – this hazardous situation may lead to serious, life-threatening adverse health consequences.**

Potassium Chloride is indicated for treatment of potassium deficiency and administered intravenously. Some containers of Product Code 2B0826, Highly Concentrated Potassium Chloride Injection, 10 mEq per 100 mL, Lot Number P319160, Exp. 06/30/2015, NDC 0338-0709-48 were incorrectly labeled on the overpouch as Highly Concentrated Potassium Chloride Injection, 20 mEq per 100 mL.

Products were distributed to customers in the U.S. between June 23, 2014 and October 2, 2014.

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 Recall Of One Lot Of Highly Concentrated Potassium Chloride Injection In The U.S. Due To Mislabeled Overpouch

Contact:
Consumer:
1-800-422-9837
Media Contacts:
John O'Malley
Deborah Spak

(224) 948-5353
media@baxter.com

FOR IMMEDIATE RELEASE — November 20, 2014, DEERFIELD, Ill. — Baxter International Inc. is voluntarily recalling one lot of Highly Concentrated Potassium Chloride Injection, 10 mEq per 100 mL to the user level due to a complaint of mislabeling of the overpouch. The inability to detect this overpouch mislabeling at the point of care may result in the administration of a dose lower than intended. In the high-risk patient population – patients prone to severe electrolyte imbalance – this hazardous situation may lead to serious, life-threatening adverse health consequences. There have been no reported adverse events associated with this issue to date.

Potassium Chloride is indicated for treatment of potassium deficiency and administered intravenously. Some containers of Product Code 2B0826, Highly Concentrated Potassium Chloride Injection, 10 mEq per 100 mL, Lot Number P319160, Exp. 06/30/2015, NDC 0338-0709-48 were incorrectly labeled on the overpouch as Highly Concentrated Potassium Chloride Injection, **20** mEq per 100 mL. Products were distributed to customers in the U.S. between June 23, 2014 and October 2, 2014. Unaffected lot numbers can continue to be used according to the instructions for use.

Baxter has notified customers, who are being directed not to 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 this drug product.

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.
- **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., through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, cancer, infectious diseases, kidney disease, trauma and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

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