Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

**DATE:** September 18, 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:** **Potassium Chloride Injection 10mEq per 100mL**

**SUMMARY:** **Unclassified Recall; The recall is being initiated due to a labeling error on the shipping cartons in a single lot. Shipping cartons labeled for this specific lot number of Potassium Chloride Injection may contain units of Gentamicin Sulfate Injection, 80 mg in 100 mL, product code 2B0862.**

**This recall affects the following lot of Potassium Chloride Injection 10mEq per 100mL:**

| Product Code | Description | Lot # | NDC # |
|---|---|---|---|
| 2B0826 | Potassium Chloride Injection 10mEq per 100mL | P318220 | 0338-0709-48 |

**The affected lot of Potassium Chloride Injection was distributed to customers in the United States between May 26, 2014, and August 8, 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 U.S. Voluntary Recall of One Lot of Potassium Chloride Injection Due to Shipping Carton Mislabeling

**Contact**
Consumer:
1-800-422-9837

Media Contacts:
John O'Malley
Deborah Spak
224-948-5353
media@baxter.com

**FOR IMMEDIATE RELEASE** - September 16, 2014 - Baxter International Inc. announced today it is voluntarily recalling one lot of Potassium Chloride Injection 10mEq per 100mL, product code 2B0826 to the hospital/pharmacy/nurse level. The recall is being initiated due to a labeling error on the shipping cartons in a single lot, which was identified by three customers. Shipping cartons labeled for this specific lot number of Potassium Chloride Injection may contain units of Gentamicin Sulfate Injection, 80 mg in 100 mL, product code 2B0862.

Potassium Chloride is indicated for treatment of potassium deficiency and administered intravenously. Gentamicin Sulfate is an antibacterial drug for intravenous administration.

As both products are packaged in 100mL containers, have similar code numbers and red labeling on the front panel, there is a potential risk of medication error or delay in therapy for patients that require high concentration potassium chloride.

The affected lot of Potassium Chloride Injection was distributed to customers in the United States between May 26, 2014, and August 8, 2014.

This recall affects the following lot of Potassium Chloride Injection 10mEq per 100mL:

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| 2B0826 | Potassium Chloride Injection 10mEq per 100mL | P318220 | 0338-0709-48 |

As part of standard clinical practice, it is recommended that healthcare professionals carefully review the product label before administering. There have been no reported adverse events associated with this situation to date.

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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