Baxter

IMPORTANT MEDICATION SAFETY ALERT

BAXTER HEPARIN SODIUM INJECTION 10,000 UNITS/ML AND HEP-LOCK U/P 10 UNITS/ML

February 6, 2007

Dear Healthcare Provider:

This important safety information concerns the potential for life threatening medication errors involving two Heparin products:

- Heparin Sodium Injection 10,000 units/mL
- HEP-LOCK U/P 10 units/mL

Baxter is aware of fatal medication errors that have occurred when two Heparin products with shades of blue labeling were mistaken for each other. **Three infant deaths resulted when the higher dosage** Heparin Sodium Injection 10,000 units/mL was inadvertently administered instead of the lower dosage of HEP-LOCK U/P 10 units/mL.

The currently marketed 1 mL vials of Heparin Sodium Injection 10,000 units/mL and the HEP-LOCK U/P 10 units/mL use shades of blue as the prominent background color on their labels.

<u>Healthcare professionals should be reminded to:</u>

- **Never rely on color as a sole indicator to differentiate product identity.**
- **Always carefully read the product label to verify that the correct product name and strength have been selected.**
- **Always carefully review both the drug name and dose on the label before dispensing and administering these products.**
- **Double-check your inventory as soon as possible, to ensure that there is no mix-up of the products.**
- **Notify all staff of the potential for errors in dispensing and administering these products. It is advised that you provide color photographs (see below) to staff to assist in their understanding of the product similarities.**

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To assist you in your review of these two labels, a side-by-side color photograph is provided below:

Baxter provides bar codes on its product labels and is considering ways to differentiate the packaging and labels to decrease the risk of medication errors. While Baxter seeks to more clearly differentiate the appearance of these two products, the Food and Drug Administration (FDA) suggests that your institution review your medication identification and administration policies and procedures. Please ensure that all staff responsible for the dispensing and administration of Heparin Sodium Injection and HEP-LOCK U/P products are aware of these medication errors and that the staff are familiar with your policies and procedures.

If you have any questions regarding this letter, please contact Baxter at 1-800-ANA-Drug (1-800-262-3784). FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of drugs and medical devices. If you suspect that a reportable adverse event related to Baxter's Heparin Sodium Injection and HEP-LOCK U/P has occurred, please report the information to Baxter and to MEDWatch at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm.

Sincerely,

[Signature]

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