



October, 2009

Dear Healthcare Provider,

The U.S. Pharmacopeia (USP) approved revisions to the monographs for Heparin Sodium and Heparin Sodium Injection. There are a number of changes to the updated monographs including, but not limited to, a new assay for heparin unit potency and a new USP reference standard with potency aligned to the World Health Organization International Standard.

These changes will impact all heparin products in the United States. The revised USP reference standard and unit definition for heparin is about 10% less potent than the former USP unit. This change became effective October 1, 2009.

Healthcare providers need to be aware of the potential decreased potency relative to product manufactured prior to October 1, 2009. The number of units on the product label will remain the same but the potency of each unit is lower due to the change in the reference standard.

Clinicians need to be aware of the decrease in mean potency and monitor each patient appropriately for their specific situation and need for anticoagulation (i.e., prophylaxis, titration to effect, and in the reversal of heparin with protamine sulfate).

Premix heparin products manufactured by Baxter Healthcare Corporation, in accordance with the new USP standards, will be differentiated by lot numbers beginning with the letter "N".

For more information, please reference the FDA Alert to Health Care Professionals:

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm184502.htm>

If you have any further questions, please contact Baxter Healthcare Corporation's Medical Information Department at 800-933-0303.

Regards,

A handwritten signature in black ink, appearing to read "J. Bradt".

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Global Medical/Clinical Affairs
Baxter Healthcare Corporation