



The Florida ESRD Network

ALERT – UPDATE 2!

Recall of Heparin Sodium Injection and Heparin Lock Flush Solution (Baxter)

FDA is providing the following recommendations to physicians, dialysis center staff, and other health care providers when using heparin sodium for injection.

- When bolus use is required, try to use a heparin product from another manufacturer or an alternate anticoagulant
- When Baxter product is the only heparin product available and use of heparin is considered to be medically necessary:
 - Administer infusions without using a bolus dose whenever possible
 - Use the lowest dose necessary at the slowest infusion rate acceptable to obtain the desired effect
 - Closely monitor the patient for adverse events, particularly hypotension and signs and symptoms of hypersensitivity, and ensure that resuscitation equipment is available.
 - Consider the potential risks and benefits in individual patients of pretreatment with corticosteroids or antihistamines before the heparin is administered. At this time FDA does not have data to determine if such pretreatment is effective.

The underlying cause for the abrupt increase in the number of adverse events reported for Baxter's heparin sodium is under investigation. FDA inspectors and scientists are working independently and in collaboration with the Centers for Disease Control and Baxter to discover the underlying cause of the adverse events. FDA personnel and laboratories are conducting intensive inspection and testing related to Baxter's heparin sodium. FDA is also seeking advice from outside experts in the manufacture and clinical use of heparin in order to help guide our investigation.

FDA continues to monitor its post-marketing safety database for additional cases and has initiated contact with international regulators to determine whether similar events have been seen in other countries with similar products. Health care providers should report any allergic-type reaction to heparin infusion to FDA's MedWatch on line at <http://www.fda.gov/medwatch/report/hcp.htm>, by fax to 1-800-FDA-0178, by mail using the postage-paid address form provided on line, or by telephone to 1-800-FDA-1088.