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Important Warnings and Instructions for Heparin Sodium Injection (Baxter)

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Transcript

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On February 11, 2008 the Food and Drug Administration issued a public health advisory titled: Important Warnings and Instructions for Heparin Sodium Injection (Baxter).

I am Pat Clarke from F-D-A's Center for Drug Evaluation and Research.

FDA is issuing this alert to:

- inform the public about reports of serious adverse events in patients who received bolus injections of heparin sodium for injection primarily from multiple-dose vials manufactured by Baxter Healthcare Corporation, and to
- recommend measures that may help to minimize these risks if this product must be used due to medical necessity.

A bolus injection means the injection of a drug or drugs in a high quantity at once, the opposite of gradual administration.

Heparin sodium is an anticoagulant (blood thinner) that is commonly administered intravenously. It is used in patients undergoing kidney dialysis, certain types of cardiac surgery, and treatment or prevention of other serious medical conditions, including deep venous thrombosis and pulmonary emboli. In many settings heparin treatment is initiated using high doses of five thousand to fifty thousand units given directly into the blood stream intravenously as a bolus.

Serious adverse events have recently been reported in patients who received these higher bolus doses. The serious adverse events include allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe

hypotension requiring treatment. Most events developed within minutes of heparin initiation although the possibility for a delayed response has not been excluded. The reports have largely involved use of multiple-dose vials. However there have been several cases in which product from multiple, single-dose vials have been combined to administer a bolus dose.

Heparin is also used in other clinical settings at lower doses or over longer periods of time; adverse events like those described above have not been seen with those uses. FDA is currently investigating whether similar adverse events have been reported for heparin products from other manufacturers.

Because of concern about the occurrence of these serious adverse events, Baxter has temporarily suspended manufacture of its multiple-dose vials of heparin sodium pending the completion of an extensive ongoing investigation to determine the root cause of the problem. Heparin is a medically necessary product and serious public health consequences would result if there were a sudden shortage of the drug. Therefore, Baxter and FDA agree that multiple-dose vials of heparin manufactured by Baxter that are currently in distribution will not be recalled. These vials may be used with caution in situations where alternative products are either not available or would be inappropriate for the individual medical situation.

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.

Heparin sodium is a pork-derived product that has been marketed in the United States for nearly 70 years. It is estimated that over 1 million multiple-dose vials of heparin are sold per month in the U.S., about half of which are manufactured and distributed by Baxter. Since late December 2007 Baxter and FDA have received nearly 350 reports of adverse reactions, and about 40 percent of the cases are estimated as serious, based upon preliminary and ongoing review. The number of reports seen in the past two months is a marked increase from the number of reports associated with heparin use normally received in a similar time period.

The majority of reported events occurred at hemodialysis centers. In early January, 2008, clusters of these allergic adverse event reports came to the attention of the CDC and to Baxter. Available data at that time suggested a link of these cases to product from specific heparin manufacturing lots. This resulted in Baxter recalling 9 product lots on January 17, 2008. FDA initiated inspections of Baxter's U.S. manufacturing plant and processes the same day.

Since the January product recall, new reports indicate that adverse events are not limited to only

the recalled heparin lots. Baxter and FDA have learned of cases occurring in hospitals where heparin was used during cardiac surgery and in patients undergoing photopheresis. Like the events associated with dialysis, most have resolved with medical management. Four patients have died since these adverse events were noted; the relationship between the deaths and the heparin use is not certain.

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 F-D-A dot GOV slash M-E-D-W-A-T-C-H slash R-E-P-O-R-T slash H-C-P dot HTM, <http://www.fda.gov/medwatch/report/hcp.htm>, by fax at 1-800-FDA-0178, by mail using the postage-paid address form provided on-line, or by telephone at 1-800-F-D-A-ten-88.

Updated information about drugs with emerging safety concerns is available 24 hours a day at our Web site W-W-W dot F-D-A dot GOV slash C-D-E-R.

Additional Information

- FDA Public Health Advisory: [Important Warnings and Instructions for Heparin Sodium Injection \(Baxter\)](#)
- Also available: [Overview Version of this Podcast](#)

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