



## FDA News

### FOR IMMEDIATE RELEASE

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### **Baxter's Multiple-dose Vial Heparin Linked to Severe Allergic Reactions** *FDA advises health care practitioners to switch suppliers and limit use of drug until problem identified*

The U.S. Food and Drug Administration announced today that Baxter Healthcare Corporation has temporarily stopped manufacturing multiple-dose vials of the injectable blood-thinning drug heparin due to reports of serious allergic reactions and hypotension (low blood pressure) in patients who receive high "bolus" doses of the drug.

Serious reactions to the drug have included difficulty breathing, nausea, vomiting, excessive sweating, and rapidly falling blood pressure that can lead to life-threatening shock. Four people have died after receiving heparin, although the relationship to the drug is unclear.

Heparin sodium is derived from pig intestines and has been marketed in the United States since the 1930s. Millions of patients benefit from the intravenous administration of this drug every year to avoid potentially life-threatening blood clots in the veins, arteries, and lungs.

"FDA concurs with Baxter's decision to halt manufacture of heparin sodium in multiple-dose vials," said Janet Woodcock, M.D., FDA's deputy commissioner for scientific and medical programs, chief medical officer, and acting director of its Center for Drug Evaluation and Research. "FDA is vigorously investigating to determine the root cause of these serious reactions associated with the use of heparin made by Baxter. In the meantime, patients and health care professionals who cannot obtain alternative sources of heparin should use caution in administering any Baxter multiple-dose vials that remain."

Heparin is commonly used before certain types of surgery, including coronary artery bypass graft surgery, and in kidney patients before they undergo dialysis. In some situations, heparin treatment is initiated using a high bolus dose given directly into the bloodstream (intravenously) over a short period of time, usually less than one hour. The reported adverse events occurred in patients who were given heparin in this form of administration. There are many other uses of heparin involving lower doses or administration over a longer period of time; adverse events have not been seen with those uses.

About 350 adverse events associated with the Baxter product have been reported since the end of last year compared to less than 100 reports in 2007. Most of the events have taken place at hemodialysis centers, almost exclusively involving patients receiving a bolus dose – which is a high dose administered over a short time. While most of the reports involve multiple-dose vials, several cases include patients who received a bolus dose after their health care professional combined heparin from single-dose vials.

The Missouri Department of Health and Senior Services first notified the Centers for Disease Control and Prevention (CDC) in January of several severe allergic-type reactions to heparin that occurred at a single pediatric hospital beginning in November. The CDC in turn alerted FDA and Baxter, prompting the company's voluntary recall of nine lots of heparin on Jan. 17.

Since then, FDA has learned of adverse events that extend beyond the recalled lots and involve patients receiving heparin for other purposes besides hemodialysis. Recent cases have included patients undergoing cardiac surgery and a specialized blood cell treatment known as photopheresis.

Over one million multiple-dose vials of heparin are sold per month in the United States; half of the vials are manufactured by Baxter of Deerfield, Ill. FDA is currently investigating whether similar events have been seen with other heparin manufacturers.

Physicians, dialysis center staff and health care providers are advised to use an alternate source of heparin or another blood-thinning drug when possible. When only Baxter product is available:

- Administer the heparin as an infusion (not a bolus) whenever possible.
- Use the lowest dose necessary at the slowest infusion rate acceptable to obtain the desired clinical effect.

- Closely monitor the patient for adverse events, particularly hypotension and signs and symptoms of hypersensitivity and ensure that resuscitation equipment is available.
- Consider pretreatment with corticosteroids (cortisone type medicines) or antihistamines (drugs that relieve the symptoms of allergic reactions) although it is not known if such pretreatment is effective.

Any allergic-type reaction to heparin infusion should be reported to FDA's MedWatch Program by phone at 800-FDA-1088, by fax at 800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, M.D. 20852-9787, or on the MedWatch Web site at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

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