



BROADCAST FAX/EMAIL ALERT

TO: DON, Medical Director, Administrator **DATE:** February 29, 2008
RE: FDA MedWatch Notice re: Baxter Heparin Recall
of pages: 1

From: U.S. Food & Drug Administration (FDA) <fda@service.govdelivery.com>

Sent: Thu, 28 Feb 2008 7:11 pm

Subject: FDA MedWatch - Heparin Sodium Injection: Recall of Multi-dose And Single-dose Vials



UPDATE - Baxter Healthcare and FDA informed healthcare professionals of a voluntary recall of all Heparin multi-dose and single-use vials, and Heparin lock flush solutions.

Audience: Surgeons, dialysis center staff, hospital risk managers, and other healthcare professionals

[UPDATE 02/28/2008] Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection, and their heparin lock flush solutions.

[Posted 02/11/2008] FDA informed healthcare professionals of important warnings and instructions for Heparin Sodium Injection use. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension. 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 sodium is an anticoagulant (blood thinner) that 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. Heparin treatment is initiated using high doses (5000-50,000 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 manufacture of multiple-dose vials of heparin sodium has been suspended pending the completion of an extensive ongoing investigation to determine the root cause of the problem. Because heparin sodium is a medically necessary product and serious public health consequences would result if there were a sudden shortage of the drug, the multiple-dose vials of heparin sodium manufactured by Baxter that are currently in distribution will not be recalled. See the FDA Public Health Advisory for Agency recommendations to healthcare professionals on the use of heparin sodium for injection.

[February 28, 2008 - [Public Health Update](#) - FDA]; [February 28, 2008 - [Press Release](#) - Baxter]

[February 11, 2008 - [Public Health Advisory](#) - FDA] UPDATED 02/28/2008 ; [February 11, 2008 - [Questions and Answers](#) - FDA]; [February 11, 2008 - [News Release](#) - FDA] Previous MedWatch alert:

[\[January 18, 2008\]](#)