



BROADCAST FAX/EMAIL ALERT

TO: Head Burse, Medical Director
DATE: February 12, 2008
RE: FDA Alert- Update re Heparin Sodium
of pages: 1

Heparin Sodium Injection (Baxter)

Audience: Surgeons, dialysis center staff, hospital risk managers, and other healthcare professionals (<http://www.fda.gov/medwatch/safety/2008/safety08.htm#HeparinInj2>)

[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 11, 2008 - [Public Health Advisory](#) - FDA <http://www.fda.gov/cder/drug/advisory/heparin.htm>

February 11, 2008 - [Questions and Answers](#) - FDA <http://www.fda.gov/cder/drug/infopage/heparin/heparinQA.htm>

[February 11, 2008 - [News Release](#) - FDA] <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01797.html>

Please visit the above Web site links to read the FDA information in its entirety. There are specific recommendations for the provision of dialysis services.