

SPINE SAFETY CAUTIONARY NOTICE:

Information for Healthcare Professionals: Intravenous Colchicine- Product Associated With Fatal Effects Including Cardiac Events And Organ Failure

According to MedWatch, FDA announced its intention to take enforcement action against companies marketing unapproved, injectable colchicine, a drug used to treat gout. Colchicine is a highly toxic drug that can easily be administered in excessive doses, especially when given intravenously. There is a narrow margin between an effective dose of the drug and a toxic dose that can result in serious health risks, including death. The FDA is aware of 50 reports of adverse events associated with the use of intravenous colchicine, including 23 deaths. Potentially fatal effects include low blood cell counts, cardiac events, and organ failure. This action does not affect colchicine products that are dispensed in tablet form.

Individuals and companies must stop making these products within 30 days and stop shipping the product within 180 days or face regulatory action. After these dates, all injectable colchicine drug products must have FDA approval to be manufactured or shipped interstate.

Read the complete 2008 MedWatch Safety Summary, including a link to the FDA News Release regarding this issue at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#colchicine>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.