

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:  
Vivitrol (naltrexone for extended-release injectable suspension):  
Medication Guide Required for Patients**

According to MedWatch, Alkermes and FDA notified healthcare professionals and patients of an update to the Warnings, Information for Patients, and Dosage and Administration sections of the Prescribing Information to strengthen language regarding the risk of injection site reactions based on postmarketing reports that had been received prior to June 2009.

FDA requires that a Medication Guide, which communicates this and other important information about treatment be provided to all patients. Healthcare professionals should also counsel patients about the risks and benefits of Vivitrol before an initial prescription, including those risks and benefits set forth in the new Medication Guide and Prescribing Information, and should ensure that patients understand these risks.

Read the complete MedWatch 2010 Safety summary, including links to the Dear HCP letter, the revised Prescribing Information and the new Medication Guide, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicinalProducts/ucm210755.htm>

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.