

SPINE SAFETY WARNING:

**Information for Healthcare Professionals:
Quinine Sulfate (Marketed as Qualaquin®): Off-Label (Not Approved by
FDA) Use of Quinine**

Quinine sulfate is approved by the FDA for treatment of uncomplicated Plasmodium falciparum malaria, a rare disease in the United States. Drug use data indicate that many prescriptions for quinine sulfate are written in this country, most likely for off-label uses (e.g., the treatment of nocturnal leg cramps). Despite taking several regulatory actions to ensure the safe use of quinine, FDA continues to receive reports of serious adverse events associated with this drug. From April 2005 through October 1, 2008, 38 domestic cases with serious outcomes were reported to FDA's Adverse Event Reporting System (AERS). Most reports were of hematologic events, including cases of thrombocytopenia, and resulted in the hospitalization of the patient. Practitioners should be aware that there are no data indicating that quinine is effective for the treatment of nocturnal leg cramps or other musculoskeletal disorders, and given the potential for life-threatening adverse events, should use extreme caution in off-label prescribing.

Read the complete article from the *FDA Drug Safety Newsletter*, at:

<http://www.fda.gov/Drugs/DrugSafety/DrugSafetyNewsletter/ucm167883.htm#QuinineSulfateMarketedasQualaquin:Off-LabelNotApprovedbyFDAUseofQuinine>.

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.