

SPINE SAFETY NOTICE:

Information for Healthcare Professionals:

Levaquin® (levofloxacin) Tablets and Oral Solution

Levaquin® (levofloxacin) Injection for Intravenous Use

Levaquin® (levofloxacin in 5% dextrose) Injection for Intravenous Use

Important Revisions to the Prescribing Information

According to MedWatch, modifications have been made to the WARNINGS and PRECAUTIONS sections of Levaquin® labeling. The revised WARNINGS and PRECAUTIONS sections address Prolongation of the QT Interval and Musculoskeletal Disorders in Pediatric Patients and Arthropathic Effects in Animals. Revised labeling specifically indicates that elderly patients may be more susceptible to drug-associated effects on the QT interval and that Levaquin® is not indicated for pediatric patients (less than 18 years of age). An increased incidence of musculoskeletal disorders (arthralgia, arthritis, tendonopathy, and gait abnormality) compared to controls has been observed in pediatric patients receiving Levaquin®.

The complete MedWatch Safety Labeling Changes, including links to prescribing information and the revised patient package insert, are available at:

<http://www.fda.gov/medwatch/SAFETY/2007/sep07.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 Web site at http://www.spine.org/spine_safety_notices.cfm. This information is provided as a service for information and education only.