

SPINE SAFETY WARNING:

**Information for Healthcare Professionals:
Important Revisions to the Prescribing Information for
Cialis® (tadalafil) Tablets
Levitra® (vardenafil hydrochloride) Tablets
Viagra® (sildenafil citrate) Tablets**

According to MedWatch, modifications have been made to the PRECAUTIONS, ADVERSE REACTIONS and PATIENT PACKAGE INSERT sections of Cialis® (tadalafil) Tablets, Levitra® (vardenafil hydrochloride) Tablets and Viagra® (sildenafil citrate) Tablets labeling. The revised PRECAUTIONS and ADVERSE REACTIONS sections inform patients and physicians that patients should stop taking PDE5 inhibitors, including Cialis®, Levitra® and Viagra®, and seek prompt medical attention in the event of sudden decrease or loss of hearing. These events, which may be accompanied by tinnitus and dizziness, have been reported in temporal association to the intake of PDE5 inhibitors, including Cialis®, Levitra® and Viagra®. It is not possible to determine whether these events are related directly to the use of PDE5 inhibitors or to other factors (see ADVERSE REACTIONS, Clinical Trials and Post-Marketing Experience). The PATIENT PACKAGE INSERT advises patients that if they experience these symptoms, they should stop taking Cialis®, Levitra® or Viagra® and contact their doctor immediately.

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

<http://www.fda.gov/medwatch/SAFETY/2007/oct07.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/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.