

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:
Pradaxa (dabigatran etexilate mesylate):
Drug Safety Communication - Safety Review of Post-Market Reports of Serious
Bleeding Events**

SOURCE: FDA MedWatch

ISSUE: FDA is evaluating post-marketing reports of serious bleeding events in patients taking Pradaxa (dabigatran etexilate mesylate). Bleeding that may lead to serious or even fatal outcomes is a well-recognized complication of all anticoagulant therapies. The Pradaxa drug label contains a warning about significant and sometimes fatal bleeds. In a large clinical trial (18,000 patients) comparing Pradaxa and warfarin, major bleeding events occurred at similar rates with the two drugs.

FDA is working to determine whether the reports of bleeding in patients taking Pradaxa are occurring more commonly than would be expected, based on observations in the large clinical trial that supported the approval of Pradaxa.

BACKGROUND: Pradaxa is a blood thinning (anticoagulant) medication used to reduce the risk of stroke in patients with non-valvular atrial fibrillation (AF), the most common type of heart rhythm abnormality.

RECOMMENDATION: At this time, FDA continues to believe that Pradaxa provides an important health benefit when used as directed and recommends that healthcare professionals who prescribe Pradaxa follow the recommendations in the approved drug label.

Patients with AF should not stop taking Pradaxa without talking to their healthcare professional. Stopping use of blood thinning medications can increase their risk of stroke. Strokes can lead to permanent disability and death.

FDA will communicate any new information on the risk of bleeding and Pradaxa when it becomes available.

Read the MedWatch safety alert, including a link to the Drug Safety Communication, at:
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm282820.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.