

SPINE SAFETY WARNING:

**Information for Healthcare Professionals:
Multaq (dronedarone): Drug Safety Communication -
Increased Risk of Death or Serious Cardiovascular Events**

SOURCE: FDA MedWatch

ISSUE: FDA notified healthcare professionals that it is reviewing data from a clinical trial that evaluated the effects of the antiarrhythmic drug Multaq (dronedarone) in patients with permanent atrial fibrillation. The study was stopped early after the data monitoring committee found a two-fold increase in death, as well as two-fold increases in stroke and hospitalization for heart failure in patients receiving Multaq compared to patients taking a placebo. FDA is evaluating whether and how the preliminary results of the PALLAS study apply to patients taking Multaq for paroxysmal or persistent atrial fibrillation or atrial flutter. The PALLAS study results are considered preliminary at this time because the data have not undergone quality assurance procedures and have not been completely adjudicated. FDA will update the public when more information is available.

BACKGROUND: Multaq is approved for use to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardiovascular risk factors, who are in sinus rhythm or who will be cardioverted.

RECOMMENDATION: At this time, patients taking Multaq should talk to their healthcare professional about whether they should continue to take Multaq for non-permanent atrial fibrillation. Patients should not stop taking Multaq without talking to a healthcare professional. Healthcare professionals should not prescribe Multaq to patients with permanent atrial fibrillation. See the Data Summary in the Drug Safety Communication for additional details.

Read the MedWatch safety alert, including a link to the FDA Drug Safety Communication, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm264204.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.