MedWatch The FDA Safety Information and Adverse Event Reporting Program

Multaq (dronedarone): Drug Safety Communication - Increased Risk of Death or Serious Cardiovascular Events

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FDA 目前審查一項臨床試驗，試驗內容是永久性心房顫動的病患使用 Multaq (dronedarone)的效果。這項試驗提前終止，原因是使用 Multaq (dronedarone)的患者比使用安慰劑的患者，增加了兩倍的死亡率，也增加了兩倍的中風機率和心衰竭導致的住院率。FDA 正在評估一項試驗(PALLAS study)是否適用於「使用 Multaq (dronedarone)的陣發性及持續性心房顫動或心房撲動的病患」，因為目前尚未確認這項試驗的品質。FDA 將隨時更新最新訊息。

非永久性心房顫動的病患應與醫療人員討論是否繼續用藥。患者不應擅自停藥。醫療人員不應開立 Multaq (dronedarone)給予永久性心房顫動的患者。

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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.

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.