MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

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

[Updated 12/19/2011]

FDA 完成一項 Multaq (droneodarone)安全性審查。這項審查說明 Multaq 會增加嚴重心血管疾病的風險，有永久性心房顫動(permanent atrial fibrillation)患者使用 Multaq 甚至會增加死亡的風險。這項審查引用的文獻來自於兩個臨床試驗：PALLAS 和 ATHENA。針對 Multaq 增加心血管疾病的風險，FDA 提供新的建議；Multaq 的仿單也修訂了使用建議：

- 有永久性心房顫動(permanent atrial fibrillation)的患者不應使用 Multaq，因為 Multaq 會增加這類患者的心血管疾病的死亡率，和中風、心衰竭的發生率。
- 使用 Multaq 時，至少每三個月使用心電圖監測心律。若有心房顫動發生，應立即停藥；若臨床需要，應治療患者的心律不整。
- Multaq 用於降低非永久性心房顫動(non-permanent AF, paroxysmal or persistent AF)的患者的住院率。
- 患者使用 Multaq 時，應接受適當的抗血栓治療。

[Updated 12/19/2011]

FDA completed a safety review of Multaq (dronedarone). This review showed that Multaq increased the risk of serious cardiovascular events, including death, when used by patients in permanent atrial fibrillation (AF). The review was based on data from two clinical trials, PALLAS and ATHENA. FDA is providing new information and recommendations for the use of Multaq to manage the potential serious cardiovascular risks with the drug.

The Multaq drug label has been revised with the following changes and recommendations:

- Healthcare professionals should not prescribe Multaq to patients with AF who cannot or will not be converted into normal sinus rhythm (permanent AF), because Multaq doubles the rate of cardiovascular death, stroke, and heart failure in such patients.
- Healthcare professionals should monitor heart (cardiac) rhythm by electrocardiogram (ECG) at least once every 3 months. If the patient is in AF, Multaq should be stopped or, if clinically indicated, the patient should be cardioverted.

- Multaq is indicated to reduce hospitalization for AF in patients in sinus rhythm with a history of non-permanent AF (known as paroxysmal or persistent AF)
- Patients prescribed Multaq should receive appropriate antithrombotic therapy

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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。

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.