



Non-aspirin Nonsteroidal Anti-inflammatory Drugs (NSAIDs): Drug Safety Communication - FDA Strengthens Warning of Increased Chance of Heart Attack or Stroke

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因阿斯匹靈以外的非類固醇抗發炎藥物(NSAIDs)使用後可能增加心臟疾病發作或中風的風險，審查相關安全訊息後，FDA 要求廠商加強所有 NSAIDs 處方藥品標籤上的警示，FDA 同時要求所有非處方類(OTC, over-the-counter) non-aspirin NSAIDs 也應更新藥品標籤上的警示內容。FDA 要求修訂標籤上的警示內容以反映以下訊息：

- 心臟疾病發作與中風的副作用最早可能在開始使用 NSAIDs 的一周內發生，長時間使用 NSAIDs 風險可能會增加。
- 使用較高劑量者，心臟疾病發作與中風的風險會增加。
- 不管本身有無罹患心臟疾病或具有危險因子，服用 NSAIDs 均有可能增加心臟疾病發作與中風的風險。
- 本身罹患心臟疾病及具有危險因子的病人服用 NSAIDs 後心臟疾病發作或中風的風險會比沒有心臟疾病及危險因子的病人高。
- 服用 NSAIDs 的病人在第一次心臟病發作後一年內死亡的可能性高於沒有服用 NSAIDs 的病人。
- 服用 NSAIDs 可能會增加心臟衰竭的風險。

建議

FDA 建議，病人與醫療專業人員需留意 NSAIDs 的心臟相關副作用，病人在服用 NSAIDs 期間如果遇到胸痛、呼吸短促、呼吸困難、身體單側無力或口齒不清的症狀需立刻就醫。

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AUDIENCE: Health Professional, Consumer

ISSUE: FDA is strengthening an existing label warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) increase the chance of a heart attack or stroke. Based on FDA's comprehensive review of new safety information, FDA is requiring updates to the drug labels of all prescription NSAIDs. As is the case with current prescription NSAID labels, the Drug Facts labels of over-the-counter (OTC) non-aspirin NSAIDs already contain information on heart attack and stroke risk. FDA will also request updates to the OTC non-aspirin NSAID Drug Facts labels.

Prescription NSAID labels will be revised to reflect the following information:

- The risk of heart attack or stroke can occur as early as the first weeks of using an NSAID. The risk may increase with longer use of the NSAID.
- The risk appears greater at higher doses.
- It was previously thought that all NSAIDs may have a similar risk. Newer information makes it less clear that the risk for heart attack or stroke is similar for all NSAIDs; however, this newer information is not sufficient for us to determine that the risk of any particular NSAID is definitely higher or lower than that of any other particular NSAID.
- NSAIDs can increase the risk of heart attack or stroke in patients with or without heart disease or risk factors for heart disease. A large number of studies support this finding, with varying estimates of how much the risk is increased, depending on the drugs and the doses studied.

- In general, patients with heart disease or risk factors for it have a greater likelihood of heart attack or stroke following NSAID use than patients without these risk factors because they have a higher risk at baseline.
- Patients treated with NSAIDs following a first heart attack were more likely to die in the first year after the heart attack compared to patients who were not treated with NSAIDs after their first heart attack.
- There is an increased risk of heart failure with NSAID use.

BACKGROUND: The risk of heart attack and stroke with NSAIDs, either of which can lead to death, was first described in 2005 in the Boxed Warning and Warnings and Precautions sections of the prescription drug labels. Since then, FDA reviewed a variety of new safety information on prescription and OTC NSAIDs, including observational studies, a large combined analysis of clinical trials, and other scientific publications. These studies were also discussed at a joint meeting of the Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee held on February 10-11, 2014.

RECOMMENDATION: Patients and health care professionals should remain alert for heart-related side effects the entire time that NSAIDs are being taken. Patients taking NSAIDs should seek medical attention immediately if they experience symptoms such as chest pain, shortness of breath or trouble breathing, weakness in one part or side of their body, or slurred speech.