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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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 FDAs 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. See the FDA Drug Safety Communication (Table 1) for a list of non-aspirin nonsteroidal anti-inflammatory drug products.

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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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