

FDA Strengthens NSAID Warning for Heart, Stroke Risks

Troy Brown, RN | July 09, 2015

The US Food and Drug Administration (FDA) has strengthened an existing label warning that nonaspirin nonsteroidal anti-inflammatory drugs (NSAIDs) may increase the risk for heart attack or stroke, according to an agency [alert](#) sent today.

Following a comprehensive review of new safety information, the FDA is requiring the drug labels of all prescription and over-the-counter (OTC) NSAIDs to be updated to reflect the increased risk. Prescription and OTC nonaspirin NSAIDs already include information about the risk for heart attack and stroke with NSAIDs, either of which can lead to death, the FDA states in a news release.

Prescription nonaspirin NSAID labels first included "Boxed Warning" and "Warnings and Precaution" sections in 2005. Since that time, the FDA reviewed new safety information on prescription and OTC NSAIDs that included observational studies, a large combined analysis of clinical trials, and other scientific publications.

The FDA's Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee discussed these studies at a joint meeting on February 10-11, 2014.

The updated labels for prescription NSAIDS will include the following information:

- Heart attack or stroke risk can increase as early as the first weeks of NSAID use, and the risk may increase with longer NSAID use. The risk appears to be greater at higher doses.
- Although the risk was previously thought to be similar for all NSAIDs, more recent information calls this into question. The FDA now says that there is insufficient information to determine whether the risk is higher or lower for one NSAID compared with another.
- A large number of studies show that patients with or without heart disease or risk factors for heart disease are at increased risk for heart attack or stroke. Study estimates of the extent of increased risk are varied, depending on the medications and doses studied.
- In general, the risk for heart attack or stroke after NSAID use is greater in patients with heart disease or risk factors for it because their risk is higher at baseline.
- Patients who take NSAIDs after a first heart attack were more likely to die in the year after the heart attack compared with those who did not take NSAIDs after their first heart attack.
- Patients are at increased risk for heart failure with NSAID use.

The FDA recommends that patients and healthcare professionals remain alert for cardiac adverse effects for the duration of NSAID use. Those taking NSAIDs should seek immediate medical attention if they have symptoms including chest pain, shortness of breath or difficulty breathing, weakness in one part or side of their body, or slurred speech.

More information on today's alert is available on the FDA [website](#).

Healthcare professionals and patients should report adverse events potentially related to NSAID use to the FDA's MedWatch Safety Information and Adverse Event Reporting Program [online](#), via fax at 1-800-FDA-0178, or via mail to the address on the pre-addressed form.

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