

FDA Strengthens Warning of Heart Attack and Stroke Risk for Non-Steroidal Anti-Inflammatory Drugs

Next time you reach into the medicine cabinet seeking relief for a headache, backache or arthritis, be aware of important safety information for non-steroidal anti-inflammatory drugs.

FDA is strengthening an existing warning in prescription drug labels and over-the-counter (OTC) Drug Facts labels to indicate that non-steroidal anti-inflammatory drugs (NSAIDs) can increase the chance of a heart attack or stroke, either of which can lead to death. Those serious side effects can occur as early as the first few weeks of using an NSAID, and the risk might rise the longer people take NSAIDs. (Although aspirin is also an NSAID, this revised warning doesn't apply to aspirin.)

The OTC drugs in this group are used for the temporary relief of pain and fever. The prescription drugs in this group are used to treat several kinds of arthritis and other painful conditions. Because many prescription and OTC medicines contain NSAIDs, consumers should avoid taking multiple remedies with the same active ingredient.



The Risks and What's New

Prescription NSAIDs are an important treatment for the symptoms of many debilitating conditions, including osteoarthritis, rheumatoid arthritis, gout and other rheumatological and painful conditions. OTC NSAIDs are used to temporarily reduce fever and to treat minor aches and pains such as headaches, toothaches, backaches, muscular aches, tendonitis, strains, sprains and menstrual cramps. Common OTC NSAIDs include ibuprofen (Motrin, Advil) and naproxen (Aleve). In addition,

some combination medicines that relieve various symptoms, such as multi-symptom cold products, contain NSAIDs.

“Be careful not to take more than one product that contains an NSAID at a time,” says Karen M. Mahoney, M.D., deputy director of FDA’s Division of Nonprescription Drug Products. How will you know? Check the list of active ingredients in the Drug Facts label (<http://www.fda.gov/drugs/resourcesforyou/ucm133411.htm>).

The labels for both prescription NSAIDs and OTC NSAIDs already

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have information on heart attack and stroke risk. In the coming months, FDA will require manufacturers of prescription NSAIDs to update their labels with more specific information about heart attack and stroke risks. FDA will also request that the manufacturers of OTC NSAIDs update the heart attack and stroke risk information in Drug Facts labels.

FDA added a boxed warning to prescription drug labels for this risk in 2005. More recent data and information are prompting FDA to update NSAID labeling. Today we know that the risk of heart attack and stroke may occur early in treatment, even in the first weeks.

“There is no period of use shown to be without risk,” says Judy Racoosin, M.D., M.P.H., deputy director of FDA’s Division of Anesthesia, Analgesia, and Addiction Products.

People who have cardiovascular disease, particularly those who recently had a heart attack or cardiac bypass surgery, are at the greatest risk for cardiovascular adverse events associated with NSAIDs.

FDA is adding information in the drug label for people who already have had a heart attack. This vulnerable population is at an increased risk of having another heart attack or

dying of heart attack-related causes if they’re treated with NSAIDs, according to studies.

But the risk is also present in people without cardiovascular disease. “Everyone may be at risk – even people without an underlying risk for cardiovascular disease,” Racoosin adds.

What Consumers Should Do

NSAIDs are effective treatments for pain, inflammation and fever. Consumers can still take them but should be aware of this increased risk of heart attack or stroke, especially at higher doses.


“As always, consumers must carefully read the Drug Facts label for all nonprescription drugs. Consumers should carefully consider whether the drug is right for them, and use the medicine only as directed. Take the lowest effective dose for the shortest amount of time possible,” Mahoney says.

When using prescription NSAIDs, read the consumer-friendly Medication Guide attached to your filled prescription, which provides important safety information.


If you have heart disease or high blood pressure, consult a health care provider before using an NSAID. Balance the benefits of NSAIDs with

the possible risks and weigh your options. If you take low-dose aspirin for protection against heart attack and stroke, you should know that some NSAIDs, including ibuprofen and naproxen, can interfere with that protective effect.

Stop taking NSAIDs and seek medical help if you experience symptoms that might signal heart problems or stroke, such as chest pain, trouble breathing, sudden weakness in one part or side of the body, or sudden slurred speech.

Reduce your risk factors for heart disease and stroke. “Smoking, high blood pressure, high cholesterol and diabetes are significant risk factors for these conditions,” Mahoney says. “If you smoke, work on quitting. See your doctor regularly to find out if you have these other strong risk factors, and commit yourself to taking care of them and of your health.” 

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