

The Arthritis Newsletter: Winter 2015

New Safety Information for Ibuprofen and Other NSAIDs: Risk of heart attack and stroke at high doses

Re-published with permission from BC Lupus Society, *THE LUPUS LIGHTHOUSE 2015 Vol. 42*

Both Canadian and US Federal Health Regulators are strengthening warning labels for non-steroidal anti-inflammatory drugs and pain relievers, adding information about the risk of heart attack and stroke in the short term. The changes apply to prescription NSAIDs, including arthritis treatments like Celebrex. US Food and Drug Administration's new warning states that heart attacks and strokes can occur in the first few weeks of taking the drugs. The agency also warns that the risks increase with higher doses of the drugs.

Although Aspirin is also an NSAID, the revised warning doesn't apply to Aspirin. Federal Health Regulators plan similar changes to over-the-counter drugs in the same class, such as pain relievers which contain Ibuprofen and other NSAIDs. Advil and Motrin are popular over-the-counter pain relievers containing Ibuprofen.

In general, patients with heart disease or risk factors for it have a greater likelihood of heart attack or stroke, the FDA noted in the announcement posted on its website. According FDA spokesman Eric Pahon "They used to say they might cause risk of heart attack or stroke. Now we are saying they do cause increased risk of heart attack and stroke".

People should check the list of active ingredients in the drug facts label if they aren't sure whether a product contains an NSAID and be careful not to take more than one product that contains an NSAID at a time, Dr. Karen Mahoney, deputy director of the FDA's Division of Nonprescription Drug Products, said in the agency's announcement.

Dr. David Henry studies the impacts of medication use at the University of Toronto. He's pleased the FDA strengthened the warnings and said "We've known about these risks for 15 years and they've been slow to get clear and coherent information out to the public". Health Canada acknowledged the risk of serious heart and stroke events on its website in April. Consumer Health Products Canada, which represents manufacturers of over-the-counter medicines, said Health Canada's warnings apply when ibuprofen is prescribed.

US labelling permits up to 10 days of consecutive use whereas the Canadian label is for up to five days for pain and three for fever, said Gerry Harrington of Consumer Health Products Canada. The US agency also added similar warnings to lower-dose, over-the-counter NSAIDs like Aleve and Advil. Those drugs currently warn patients to take the lowest dose possible for as short a period as possible. They are not intended to be used for pain longer than 10 days, according to their labels.

In light of these new warnings and since lupus patients are considered to have a higher risk of heart disease, please discuss the use of NSAIDS with your rheumatologist or your doctor.

In the United States 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.

New Safety Information for Prescription-strength Ibuprofen: Risk of heart attack and stroke at high doses

Health Canada is working with the Canadian manufacturers of prescription oral ibuprofen products to update the safety information regarding the risk of serious cardiovascular side effects (e.g., heart attack and stroke) when these products are used at high doses (at 2400 mg/day). This risk increases with dose and duration of use.

Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) used for pain and fever relief, and to reduce inflammation. The majority of ibuprofen products in Canada are available over-the-counter. These products have a maximum recommended dose of 1200 mg per day and are to be used for a short duration of time (seven days or less). No evidence of an increased cardiovascular risk has been found with over-the-counter ibuprofen when used as directed.

Serious heart- and stroke-related events are a known risk with all NSAIDs and the prescribing information contains extensive warnings on this risk.

Note: This list may not be complete

NON-ASPIRIN NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)

Generic name	Brand names
celecoxib	Celebrex
diclofenac	Cambia, Cataflam, Dyloject, Flector, Pennsaid, Solaraze, Voltaren, Voltaren-XR, Zipsor, Zorvolex, Arthrotec (combination with misoprostol)

diflunisal	No brand name currently marketed
etodolac	No brand name currently marketed
fenoprofen	Nalfon
flurbiprofen	Ansaid
ibuprofen*	Advil, Caldolor, Children's Advil, Children's Elixsure IB, Children's Motrin, Ibu-Tab, Ibuprohm, Motrin IB, Motrin Migraine Pain, Profen, Tab-Profen, Duexis (combination with famotidine), Reprexain (combination with hydrocodone), Vicoprofen (combination with hydrocodone)
indomethacin	Indocin, Tivorbex
ketoprofen	No brand name currently marketed
ketorolac	Sprix
mefenamic acid	Ponstel
meloxicam	Mobic
nabumetone	No brand name currently marketed
naproxen*	Aleve, Anaprox, Anaprox DS, EC-Naprosyn, Naprelan, Naprosyn, Treximet (combination with sumatriptan), Vimovo (combination with esomeprazole)
oxaprozin	Daypro
piroxicam	Feldene
sulindac	Clinoril
tolmetin	No brand name currently marketed

*There are many over-the-counter (OTC) products that contain this medicine.