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NEW NSAID WARNING FROM THE FDA

The FDA is requiring prescription nonaspirin nonsteroidal anti-inflammatory drug (NSAID) labels to include information on heart attack and stroke risk.

This update strengthens an existing label warning that NSAIDs increase the risk for heart attack or stroke. The FDA is making this change after reviewing new safety information on prescription and over-the-counter NSAIDs.

Some of the new information for the updated labels includes:

1. The risk for heart attack or stroke can occur as early as the first weeks of using an NSAID.
2. The risk appears greater at higher doses.
3. NSAIDs can increase the risk for heart attack or stroke in patients with or without heart disease or risk factors for heart disease. There is also an increased risk for heart failure with NSAID use.

The agency will request similar label updates for over-the-counter nonaspirin NSAIDs.

Individuals taking NSAIDs should seek medical help immediately for symptoms of chest pain, shortness of breath, trouble breathing, weakness in one part or side of the body or slurred speech, according to the FDA. The agency recommends that patients and health care providers watch for heart-related side effects for the entire time NSAIDs are being taken, and to report side effects to the MedWatch program.

The Cox-2 inhibitors were developed to minimize the GI complications experienced with other NSAIDs. Vioxx is a Cox-2 inhibitor which was taken off of the market because of the number of deaths it caused. According to David J. Graham, MD, MPH (Associate Director for Science, Office of Drug Safety, US FDA) 139,000 Americans suffered from serious side-effects due to Vioxx and between 26,000 and 55,000 died from using the drug. Now we are finding that there may be problems with other NSAIDs as well.

NSAIDS & ANTIDEPRESSANTS —A DEADLY COMBO

The *British Medical Journal* (2015;351:h3517) published a study that looked at the risk of intracranial hemorrhage among patients treated with antidepressants and non-steroid anti-inflammatory drugs (NSAIDs), compared with the risk among those treated with antidepressants without NSAIDs. The subjects were patients who began receiving antidepressants for the first time (index date) without a history of having received a prescription for antidepressants during the preceding year. Patients who had been diagnosed as having cerebrovascular diseases within a year before the index date were excluded.

The main outcome measure was time to first hospital admission with intracranial hemorrhage within 30 days after drug use. The researchers, from Seoul National University College of Medicine, looked at data from over four million people who had started taking antidepressant medication between 2009 and 2013. About half were also prescribed an NSAID, like ibuprofen or naproxen. The team used hospital records to see who was admitted for intracranial bleeding in the 30 days after being prescribed the NSAID. They found that intracranial

hemorrhage is increased in patients who combine antidepressants and NSAIDs, like ibuprofen or naproxen. The study results are particularly relevant since depression and chronic pain often go hand-in-hand, and millions of people may take the two meds together.

It turned out that people who began taking both medications had a 60% greater risk of intracranial hemorrhage than people taking only antidepressants. There was no significant difference in the risk among the different types of antidepressants (SSRIs, SNRIs, and tricyclics).

The risk of intracranial bleeding was especially heightened in men who took both antidepressants and NSAIDs. Their risk was about 2.6 times higher than men who took antidepressants alone, whereas the risk for women was only about 1.2 times higher than women who took just the one medication.

The researchers only looked at bleeding that occurred within 30 days of the NSAID prescription: The risk might be different — possibly higher — over the long-term. Also, they only looked at patients taking prescription NSAIDs, not over-the-counter painkillers.

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Each medication seems to inhibit platelets, and each is thought to slightly increase the risk of bleeding on its own (for instance, SSRI antidepressants and NSAIDs are both known to increase the risk of gastrointestinal bleeding).

This study comes just days after the FDA strengthened its warning about the risk of heart attack and stroke from NSAIDs alone. The FDA notes that although heart attack and stroke risk may occur within weeks of beginning to take an NSAID, the risk is likely higher with long-term use.

About 65% of people with major depression also have chronic pain, according to an editorial that accompanied the main study. This makes it doubly important for you to have effective natural alternatives for these patients.

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SAVE A LIFE—IT MAY BE YOUR OWN

Recent warnings about NSAID use from the FDA and research in the *British Medical Journal* pose new concerns for patients taking pain medication. We have known the dangers of pain medications for decades. According to research appearing in the July 27, 1998 issue of the *American Journal of Medicine*, “Conservative calculations estimate that approximately 107,000 patients are hospitalized annually for nonsteroidal anti-inflammatory drug (NSAID)-related gastrointestinal (GI) complications and at least 16,500 NSAID-related deaths occur each year among arthritis patients alone. The figures for all NSAID users would be overwhelming, yet the scope of this problem is generally under appreciated”

Other research links pain medications to high blood pressure, kidney failure, heart failure, ulceration of the GI tract, and some drugs even interfere with bone repair. In the July 23, 1996 *Archives of Internal Medicine*, it states that in nearly 2,000 arthritic patients studied, ulcer risk increased 10-fold. It also stated that almost 25% of NSAID users have ulcers, most of which are without symptoms.

NSAID use perpetuates the very problem that it is designed to treat. Their use actually increases the body’s oxidative stress—leading to further inflammation. Research articles appearing in the journals *Pharmacological Research Communications* and the *Lancet* have demonstrated that NSAIDs interfere with

the formation of cartilage. So someone with arthritis who takes these drugs is trading short-term relief for long-term degeneration. Elderly patients with arthritis especially need to pay attention to diet and lifestyle. Getting painful joints moving and strengthening the muscles associated with them is often helpful. Finding safer, natural alternatives to pain medication can literally save lives. Consider the ideas below as alternatives to dangerous drugs:

The anti-inflammation diet: Go to WholeHealthWeb.com and download our free report, “Eat Your Way Out of Pain”. Dietary changes can reduce pain. Avoiding sugar, refined grains and chemical additives will help reduce inflammation. Eating anti-inflammatory foods, like brightly colored fruits and vegetables also help to reduce pain. The free report at WholeHealthWeb.com will give you a detailed plan and sample menus.

Herbal & other natural remedies Various herbs, like *Harpagophytum procumbens* (Devil’s claw), *Boswellia serrata* (Boswellia), and *Salix alba* (White Willow Bark) can help to reduce pain naturally. Curcumin, omega-3 fatty acids and pancreatic enzymes (enzymes to be taken on an empty stomach) can all help to reduce inflammation

Glucosamine and chondroitin products: These supply important nutrients to support the structure and function of joint cartilage.

**True
compassion
means not only
feeling
another's pain
but also being
moved to help
relieve it.**

**Daniel
Goleman**

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DEPRESSION AND INFLAMMATION

A recent editorial in the *British Medical Journal* states that 65% of patients with depression also suffer from chronic pain (see pages 2-3). They also published a study that shows the dangers of medicating these two problems simultaneously. Fortunately, there are natural approaches that can help with anxiety, depression and sleep disorders.

Exercise: There are so many studies that show exercise to help people suffering from anxiety and depression. Some studies even show exercise outperforming medication. In the *Journal of the American Medical Association* (January 28, 1983;249 (4):459-460), 41 insomniacs were studied (23 women and 18 men). It was found that developing good sleep habits, doing regular relaxation exercises before bedtime, and reducing daytime stress helped in the reduction of medications within six weeks.

Diet: A pure diet—free of additives, hydrogenated oil, sugar and refined food does amazing things to improve mood and energy.

Magnesium is nature's muscle relaxer. It is involved in over 300 enzyme systems—including those involved

with producing neurotransmitters. Magnesium is also necessary to ensure good sleep. Magnesium will be depleted in people taking diuretics and who eat a lot of sugar and processed foods.

B vitamins Thiamin, and other B vitamins will be depleted in people who eat processed food. Thiamin is also destroyed by some medications. People who are thiamin deficient tend to fall asleep for a short time and wake up, unable to go back to sleep. They are also to have negative thoughts, often having feelings of impending doom.

Vitamin B₁₂: A study appearing in the journal *Sleep* (1990;13(1):15-23) cited case studies where B₁₂ supplementation helped with sleep disturbance. B₁₂ deficiency is also associated with depression.

Beta-Phenyl-gamma-aminobutyric acid is a derivative of GABA. GABA is an inhibitory neurotransmitter (it is the substance that many anti-anxiety medications work to increase). Phenibut has been shown to have a calming effect and assist in instances of stress, anxiety and even the improvement of impaired sleep. However, due to its derivation of GABA. It should not be taken with alcohol, sedatives or MAOIs.