

Consumer Health Alert:

FDA Highlights the Dangers of Acetaminophen and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

In January 2004, the Food and Drug Administration initiated a consumer education initiative designed to increase awareness of the potential dangers associated with commonly used pain relievers such as acetaminophen and NSAIDs. The campaign utilizes public announcements, advisory letters to pharmacists, consumer awareness brochures, and new guidelines for the labeling of these products.

Selected Statements from the FDA Education Program†

U.S. Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

"The campaign is intended to raise consumer awareness of these safety issues (bleeding, kidney and liver damage) and to inform healthcare providers about the role that they can play in preventing acetaminophen induced hepatotoxicity and NSAID-related gastrointestinal bleeding and renal toxicity in patients using these medicines."

Key point: The public is generally unaware of the health risks posed by NSAIDs.

"Acetaminophen is safe and effective when used correctly, but taking too much can lead to liver damage, and even death. The risk for liver damage may be increased in consumers who drink three or more alcoholic beverages per day while using acetaminophen-containing medicines."

Key point: Acetaminophen can cause liver damage and even death.

"NSAIDs can cause stomach bleeding with an increased risk in consumers who are over 60, are taking prescription blood thinners, are taking steroids or have a history of stomach bleeding. NSAIDs may also increase the risk of irreversible kidney problems in consumers with preexisting kidney disease, or who are taking a diuretic."

Key point: NSAIDs can cause stomach bleeding and kidney damage.

Facts about Acetaminophen and NSAIDs*:

- NSAID-induced disease causes at least 103,000 hospitalizations per year.
- Every year 16,500 arthritis patients die from NSAID-related gastrointestinal damage alone.
- 21% of all adverse drug reactions are due to NSAID use.
- People over 60 have a significantly higher probability of experiencing complications associated with NSAID use.

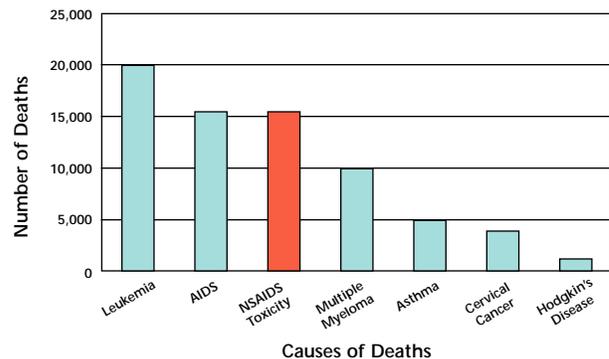
†For more information please visit www.fda.gov

*For references or additional information, please visit: www.postgradmed.com/issues

Yet there are over 13 million regular users of NSAIDs in the United States, with at least 30 billion over-the-counter NSAID tablets sold annually.

NSAIDs Associated Health Risks: The "Silent Epidemic"

"If deaths from gastrointestinal toxic effects from NSAIDs were tabulated separately in the National Vital Statistics reports, these effects would constitute the 15th most common cause of death in the United States. Yet these toxic effects remain mainly a 'silent epidemic', with many physicians and most patients unaware of the magnitude of the problem. Furthermore the mortality statistics do not include deaths ascribed to the use of over-the-counter NSAIDs."



Wolfe M M, Lichtenstein D R, and Singh G. Gastrointestinal Toxicity of Nonsteroidal Anti-inflammatory Drugs. *New England Journal of Medicine* 1999;(24):188-89.

Safe, Natural Alternatives to NSAIDs

Recent advancements in nutritional science have led to the development of highly effective natural strategies to control pain and inflammation. The use of genetic and cellular testing technology has allowed researchers to identify natural compounds that duplicate the effectiveness of drugs without the negative side effects.

Ask your healthcare professional about natural, safe, and effective alternatives to potentially harmful pain medications. Pain management can be achieved without the potentially life-threatening side effects associated with acetaminophen and NSAIDs. Don't become a statistic in the **silent epidemic**.