

# U.S. warns of stomach, liver problems from painkillers

*Last Updated: Tuesday, April 28, 2009 / 3:33 PM ET*

[CBC News](#)

Pain and fever medications such as Tylenol and Advil will carry new warning labels to highlight potential safety risks such as internal bleeding and liver damage, the U.S. Food and Drug Administration said Tuesday.

The drugs include acetaminophen (Tylenol) and non-steroidal anti-inflammatory drugs (NSAIDs) including Aspirin, ibuprofen (Advil, Motrin and other brands), naproxen (Aleve and other brands) and ketoprofen.

The new labels aim to alert consumers to potential liver damage from acetaminophen and the potential for stomach bleeding from NSAIDs.

"Acetaminophen and NSAIDs are commonly used drugs for both children and adults because they are effective in reducing fevers and relieving minor aches and pain, such as headaches and muscle aches," Dr. Charles Ganley, director of the FDA's office of nonprescription drugs in the Center for Drug Evaluation and Research, said in a statement.

"However, the risks associated with their use need to be clearly identified on the label so that consumers taking these drugs are fully aware of the potential harm they can cause. It is important that they know how to take these medications safely to reduce their risk."

Products with acetaminophen will carry the warning that it may cause severe liver damage if the maximum daily dose is exceeded, or if other drugs are taken with acetaminophen, or if three or more alcoholic drinks a day are consumed while taking the drug.

The new label will also say people should consult their doctor before taking acetaminophen if they are also taking the blood thinner warfarin.

## Label changes underway

The risk for stomach bleeding may increase in people who use NSAIDs and who are taking blood-thinning drugs or steroids, the FDA said.

Stomach bleeding is also an increased risk for people who take multiple NSAIDs at the same time, or in people who take them longer than directed. Alcohol use can increase the risk for stomach bleeding with NSAID use.

Signs of stomach bleeding include stomach pain that doesn't go away, vomiting blood or blood in the stool.

The changes were first proposed in late 2006, and also apply to generic drugs and cold medications that contain painkillers.

Some companies have already started to change the labels on their products, which must be done by next April, Matthew Holman, deputy director of FDA's Division of Nonprescription Regulation Development in the office of nonprescription products, told reporters.