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News & Events

FDA NEWS RELEASE

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FDA limits acetaminophen in prescription combination products; requires liver toxicity warnings

Agency strategy caps maximum at 325 milligrams to reduce risk of liver toxicity

The U.S. Food and Drug Administration is asking manufacturers of prescription combination products that contain acetaminophen to limit the amount of acetaminophen to no more than 325 milligrams (mg) in each tablet or capsule.

The FDA also is requiring manufacturers to update labels of all prescription combination acetaminophen products to warn of the potential risk for severe liver injury.

Acetaminophen, also called APAP, is a drug that relieves pain and fever and can be found in both prescription and over-the-counter (OTC) products. It is combined in many prescription products with other ingredients, usually opioids such as codeine (Tylenol with Codeine), oxycodone (Percocet), and hydrocodone (Vicodin). OTC acetaminophen products are not affected by today's action.

“FDA is taking this action to make prescription combination pain medications containing acetaminophen safer for patients to use,” said Sandra Kweder, M.D., deputy director of the Office of New Drugs in FDA’s Center for Drug Evaluation and Research (CDER). “Overdose from prescription combination products containing acetaminophen account for nearly half of all cases of acetaminophen-related liver failure in the United States; many of which result in liver transplant or death.”

The elimination of higher-dose prescription combination acetaminophen products will be phased in over three years and should not create a shortage of pain medication. Patients and health care professionals are being notified of the new limitation on acetaminophen content, and of the labeling change, in a drug safety communication issued by CDER. The FDA believes that prescription combination products containing no more than 325 mg of acetaminophen per tablet are effective for treating pain.

“There is no immediate danger to patients who take these combination pain medications and they should continue to take them as directed by their health care provider,” said Kweder. "The risk of liver injury primarily occurs when patients take multiple products containing acetaminophen at one time and exceed the current maximum dose of 4,000 milligrams within a 24-hour period.”

Acetaminophen is also widely used as an over-the-counter pain and fever medication, and is combined with other OTC ingredients, such as cough and cold ingredients. The actions FDA is taking for prescription acetaminophen products do not affec OTC acetaminophen products.

Because of continued reports of liver injury, FDA proposes that boxed warnings, the agency’s strongest warning for prescription drugs, be added to all acetaminophen prescription products. Most of the cases of severe liver injury occurred in patients who took more than the prescribed dose of an acetaminophen-containing product in a 24-hour period, took more than one acetaminophen-containing product at the same time, or drank alcohol while taking acetaminophen products.

An FDA advisory committee discussed the issue at a meeting in June, 2009, and recommended strengthening the warning about severe liver injury on the drug labels of prescription products containing acetaminophen.

For more information and a list of affected products, please visit: www.fda.gov/acetaminophen [1]

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