PATIENT SAFETY BLOG

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FDA sets new limits for prescription combination products with acetaminophen

To avoid the risk of "severe liver injury," the Food and Drug Administration (FDA) wants manufacturers of prescription combination products containing acetaminophen to limit the amount of acetaminophen to no more than 325 milligrams (mg) in each tablet or capsule. Manufacturers also will have to update warning labels on these products to alert consumers about the potential risks.

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Acetaminophen, better known as Tylenol, its most popular brand name, is a pain reliever and fever reducer sold over the counter (OTC) as well as in prescription products in combination with other ingredients, such as codeine (Tylenol & Codeine), oxycodone (Percocet) and hydrocodone (Vicodin). The FDA action affects prescription products only, not OTC medications.

“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 3 years. “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,” Kweder said. "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.”

Because of continued reports of liver injury, FDA also wants to see boxed warnings, the agency’s strongest warning for prescription drugs, 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-

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hour period, took more than one acetaminophen-containing product at the same time or drank alcohol while taking acetaminophen products.

Source: Food and Drug Administration.

Click here for more information and a list of affected products.

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