

US urges acetaminophen limits due to liver risks

15 January 2014

US regulators said Wednesday they are urging doctors to cease prescribing drugs that contain more than 325 milligrams of acetaminophen per tablet due to concerns over liver damage.

Still, "inadvertent overdose" from prescription combination drugs containing acetaminophen make up about half of all cases of [acetaminophen](#)-related liver failure in the nation, the FDA said.

Prescription painkillers such as Vicodin and Percocet, can contain acetaminophen and may be dangerous if taken with other popular pain-relievers, like Tylenol, or with alcohol.

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"There are no available data to show that taking more than 325 milligrams of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for [liver injury](#)," the Food and Drug Administration said.

"Limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, [liver transplant](#), and death."

The maximum dose per day for adults is 4,000 milligrams.

To avoid exceeding that level, the FDA called on patients to refrain from taking more than one drug at a time containing acetaminophen, and to avoid such medicines if they drink more than three alcoholic beverages daily.

The FDA also recommended that [health care providers](#) consider prescribing combination drug products that contain 325 milligrams or less of acetaminophen, known as paracetamol outside North America.

The FDA asked prescription drug manufacturers in 2011 to limit the amount of acetaminophen to no more than 325 milligrams in each tablet or capsule in order to protect consumers.

As of January 14, more than half have voluntarily complied, the agency said.

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