Using Non-Opioid Medications: Recognizing Total Acetaminophen Intake

The labels on some over-the-counter acetaminophen products currently instruct patients to avoid consuming more than 3000 mg daily of that specific product, and to avoid total daily amounts of acetaminophen exceeding 4000 mg.

Acetaminophen is available in various OTC products in combination with other compounds, including aspirin, caffeine, antihistamines, and decongestants and in combination with a variety of opioids in prescription drug products (e.g., Vicodin, Tylox, Percocet, Roxicet, Roxilox).

Patients who take OTC cough and cold remedies that contain acetaminophen may unknowingly exceed the maximum daily dose if they are also taking prescription pain medications containing acetaminophen. To add to the problem, prescription drugs containing acetaminophen may not be labeled as such, or may use an unfamiliar abbreviation (APAP).

Many outpatients remain confused about using acetaminophen safely, signaling the need for more effective patient education to prevent unintentional harm. Even hospitalized patients may be at risk. In one study, 6.6% of those receiving acetaminophen exceeded the 4 g per day maximum recommended dose; nearly 25% of these patients were 65 years or older. Unless the risk of unintentional overdose is taken seriously and patients are educated about the need to limit the total daily dose, serious hepatotoxicity can occur.

In January 2014, FDA recommended that physicians discontinue prescribing and dispensing prescription combination drug products that contain more than 325 milligrams (mg) of acetaminophen per tablet, capsule, or other dosage unit. There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the increased risk for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can otherwise lead to liver failure, liver transplant, and death.
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Citations

FDA Drug Safety Communication: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure. www.fda.gov/drugs/drugsafety/ucm239821.htm.
