

SPINE SAFETY WARNING:

**Information for Healthcare Professionals:
Acetaminophen Prescription Products Limited to 325 mg Per Dosage Unit:
Drug Safety Communication**

Source: FDA MedWatch

Audience: Pharmacy, Pain Management

Issue: FDA notified healthcare professionals that it has asked drug manufacturers to limit the strength of acetaminophen in prescription drug products, predominantly combinations of acetaminophen and opioids, to 325 mg per tablet, capsule, or other dosage unit, making these products safer for patients. This action will help to reduce the risk of severe liver injury and allergic reactions associated with acetaminophen. A Boxed Warning highlighting the potential for severe liver injury and a Warning highlighting the potential for allergic reactions (swelling of the face, mouth, and throat, difficulty breathing, itching, or rash) will be added to the label of all prescription drug products that contain acetaminophen.

Background: Acetaminophen, one of the most commonly used drugs in the United States, is widely and effectively used in both prescription and over-the-counter (OTC) products to reduce pain and fever. Examples of prescription products that contain acetaminophen include hydrocodone with acetaminophen (Vicodin, Lortab), and oxycodone with acetaminophen (Tylox, Percocet). OTC products containing acetaminophen (e.g., Tylenol) are not affected by this action. Information about the potential for liver injury is already required on the label for OTC products containing acetaminophen. FDA is continuing to evaluate ways to reduce the risk of acetaminophen related liver injury from OTC products. No drug shortages are expected, because the 3-year implementation period should permit adequate time for necessary reformulations.

Recommendation: Healthcare professionals were reminded to advise patients not to exceed the acetaminophen maximum total daily dose (4 grams/day), and not to drink alcohol while taking acetaminophen-containing medications.

Healthcare professionals were encouraged to inform patients that there is no immediate danger to patients who take these combination pain medications, and patients should continue to take them as directed by their health care provider. The Drug Safety Communication provides additional information for healthcare professionals, information for patients, a data summary and a list of all affected products.

Read the MedWatch safety alert, including links to the FDA Drug Safety Communication, Q&As, and Consumer Update, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm239955.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.