MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

# Acetaminophen Prescription Combination Drug Products with more than 325 mg: FDA Statement - Recommendation to Discontinue Prescribing and Dispensing

**[Posted 01/14/2014]**

FDA建議醫療人員停止處方和調劑acetaminophen含量超過325 mg的複方藥品。沒有數據證明：使用acetaminophen含量超過325 mg的複方藥品所提供的益處會高於肝損傷的風險。限制產品的acetaminophen劑量，可降低使用acetaminophen致過量的情形，藉以減少肝損傷、肝衰竭、肝移植、死亡。

使用acetaminophen致嚴重肝損傷的案例發生在：

- 在24小時內，使用acetaminophen產品超出處方劑量；
- 同時服用多種acetaminophen產品，或
- 飲酒併用acetaminophen產品。

**背景**

2011年1月，FDA要求製造商於2014年1月14日前之前，限制acetaminophen產品含量不可超過325 mg。藉此可避免消費者使用過量的acetaminophen而造成嚴重肝損害。Acetaminophen常與另一種成分(鴉片類藥物)併用，用於止痛。

Acetaminophen是最廣泛使用的非處方止痛緩解發燒的藥。消費者一不小心就會使用過量。

超過半數的製造商已遵照FDA的要求。然而，仍有部分acetaminophen含量超過325 mg的複方藥品可使用，FDA將撤銷其許可證。

**建議**

- 醫療人員應考慮處方含acetaminophen含量在325 mg以下之複方藥品。
- 藥師接獲含acetaminophen成分含量超過325mg之複方藥品處方時，應與醫師討論處方含量小於325 mg之acetaminophen複方藥品。
- 必要時仍可使用兩錠(膠囊)之劑量，總量為650 mg。
- 醫療人員處方acetaminophen與opioid類藥品之複方產品時，應注意各別成分含量。

**本院Acetaminophen複方品項**

| Chlorzoxazone & Acetaminophen (Ancogen)<br>安可腱 250 & 300 mg/tab | Tramadol & Acetaminophen (Ultracet)<br>及通安37.5 & **325** mg/tab【管4】 |
|---|---|
|  |  |

**[Posted 01/14/2014]**

**AUDIENCE:** Consumer, Dentistry, Emergency Medicine, Internal Medicine, Pharmacy, Pain Management, Surgery

**ISSUE:** FDA is recommending health care professionals 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 added risks 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 lead to liver failure, liver transplant, and death.
Cases of severe liver injury with acetaminophen have 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.

**BACKGROUND:** In January 2011 FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage which can result from taking too much acetaminophen. This category of prescription drugs combines acetaminophen with another ingredient intended to treat pain (most often an opioid), and these products are commonly prescribed to consumers for pain, such as pain from acute injuries, post-operative pain, or pain following dental procedures.
Acetaminophen is also widely used as an over-the-counter (OTC) pain and fever medication, and is often combined with other ingredients, such as cough and cold ingredients. FDA will address OTC acetaminophen products in another regulatory action. Many consumers are often unaware that many products (both prescription and OTC) contain acetaminophen, making it easy to accidentally take too much.
More than half of manufacturers have voluntarily complied with the FDA request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.
**RECOMMENDATION:** FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that they contact the prescriber to discuss a product with a lower dose of acetaminophen. A two tablet or two capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.