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Drugs

FDA recommends health care professionals discontinue prescribing and dispensing prescription combination drug products with more than 325 mg of acetaminophen to protect consumers

[1/14/2014] 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.

We recommend that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. We also recommend 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 65 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.

In January 2011 we asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen² to no more than 325 mg in each tablet or capsule by January 14, 2014. We 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.

More than half of manufacturers have voluntarily complied with our request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available.

In the near future we intend 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.

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.

Inadvertent overdose from prescription combination drugs containing acetaminophen accounts for nearly half of all cases of acetaminophen-related liver failure in the United States, some of which result in liver transplant or death.

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. We 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.

Health care providers and pharmacists who have further questions are encouraged to contact the Division of Drug Information at 888.INFO.FDA (888-463-6332) or druginfo@fda.hhs.gov.

Related Resources

- Acetaminophen Withdrawal Request Letter (PDF - 30KB)³
[template]
- Federal Register Notice: Prescription Drug Products Containing Acetaminophen; Actions To Reduce Liver Injury From Unintentional Overdose⁴
- Don't Double Up on Acetaminophen⁵ Taking acetaminophen? Know the right dose.

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA



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