

Acetaminophen Safety

Key Points

- **According to the FDA, intentional and unintentional acetaminophen overdoses leading to severe hepatotoxicity continue to occur in the US.**
- **In the last 6 months, over 200 Idaho Medicaid patients were prescribed acetaminophen-containing prescription drugs that appeared to be for more than the maximum daily recommended dose for more than 30 days.**

Severe adverse events related to prescription and over-the-counter medications are an increasing problem in the United States.^{1,2} Acetaminophen is of particular concern due to its wide use and risk of hepatotoxicity. While it is generally considered safe when used according to the directions on its labeling and millions of doses are administered safely every year, taking higher than recommended doses or even moderate doses chronically can cause liver damage and even death.

In May of this year the FDA released a report stating "recent studies indicate that unintentional and intentional overdoses leading to severe hepatotoxicity continue to occur." According to studies conducted between 1990 and 1998, acetaminophen-related overdoses cause 56,000 emergency room visits, 26,000 hospitalizations, and 458 deaths annually.³ Many such overdose cases likely occurred in patients taking more than one product containing acetaminophen without knowing it.

In June an advisory committee reviewed an FDA report recommending stronger warning labels, better consumer education, and a lower daily dosage limit of 3,250 mg (from 4,000 mg). The committee voted (21 to 16) to reduce the current allowable maximum daily dose of acetaminophen from 4,000 mg and to reduce the single dose from 1,000 mg to 650 mg.

The committee also voted (20 to 17) that acetaminophen combination prescription products be eliminated. Prohibiting these products would impact clinical practice substantially. Although abuse or overuse of narcotic analgesics that contain acetaminophen is occurring with increasing frequency and likely responsible for the majority of acetaminophen overdoses, millions of doses of these products are dispensed every year. In fact, according to the FDA, the combination of hydrocodone and acetaminophen has been the most frequently dispensed drug since 1997. The FDA will likely make final decisions on these advisory committee recommendations within the next few months.

A review of the Idaho Medicaid population over the last 4 years shows that the proportion of users of acetaminophen-containing prescription drugs that receive excessive amounts is less than 1%. However, more than 200 patients in the last 6 months appeared to have received more than the maximum daily recommended dose for more than 30 days. The majority of the claims were for combination hydrocodone and acetaminophen. These data highlight the need for closer monitoring of patients prescribed these drugs and better education for patients regarding dosage limits and the acetaminophen content of available over-the-counter products.

References

1. Manchikanti L, Singh A. Therapeutic opioids: A ten-year perspective on the complexities and complications of escalating use, abuse, and nonmedical use of opioids. *Pain Physician* 2008;11(suppl):S63-88.
2. Utah Health Status Update: Prescription Medication Overdose Deaths in Utah. Utah Department of Health. November 2008. Accessed online September 4, 2009 at http://health.utah.gov/opha/publications/hsu/08Nov_RxDrugDth.pdf.
3. Nourjah P, Ahmad SR, Karwoski C, et al. Estimates of acetaminophen (Paracetomal)-associated overdoses in the United States. *Pharmacoepidemiol Drug Saf.* 2006 Jun;15(6):398-405.

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