

FDA Limits the Dosage of Acetaminophen

Background

In response to findings of possible liver toxicity with over-use of acetaminophen, on January 13th 2011, the FDA asked drug manufacturers to limit combination products containing acetaminophen to 325mg per dose¹. This is seen as a significant development for Workers' Compensation claimants, who consume many versions of medications containing acetaminophen. With current narcotic and acetaminophen combinations ranging up to 650mg of acetaminophen, this new regulation will reduce the acetaminophen content in some medications by 50%. The new regulation will likely be implemented over a 3-year period. This should give manufacturers ample time to make appropriate changes.

Acetaminophen, alone or in combination with other active drugs, acts as a pain reliever and fever reducer. Acetaminophen is found in common OTC products such as:

- Tylenol™
- Nyquil™
- Excedrin™
- Theraflu™

Acetaminophen is also found in prescription products including:

- Percocet™
- Lortab™
- Vicodin™
- Ultracet™

Although well accepted by the medical community, acetaminophen use does not come without precautions and side-effects. Currently, the FDA recommends a maximum dose of 1,000 milligrams (1 gram) of acetaminophen in a single dose, and 4,000-milligrams (4 grams) maximum per day. This is done to combat potential liver toxicity.

When taken according to FDA-approved labeling, acetaminophen is a relatively safe drug. However, with so many over-the-counter and prescription items containing acetaminophen, taking combinations of these drugs can cause cumulative toxicity. With lower strengths of acetaminophen-containing products available in the future, there may be fewer cases of overdose and toxicity.

Economic Impact of this new regulation:

A review of prices for Lortab and Vicodin (hydrocodone with acetaminophen) and Percocet (oxycodone and acetaminophen) indicates that there are price differences in the respective milligram strengths. There are isolated examples of manufacturers who price their lower-strength acetaminophen products higher. For example among the oxycodone with acetaminophen products, there are price increases in the range of \$0.10 to \$0.20 per tablet for products with lower-content, 325-milligram levels of acetaminophen².

Where We Stand

We believe that the new FDA regulation will likely decrease the risk of accidental acetaminophen overdose from occurring and improve the safety profile of this medication. However, future cost increases due to these new acetaminophen regulations could result in a cost increase for Cypress Care clients. To protect our Workers' Compensation claimants, Cypress Care maintains a real-time Drug Utilization Review engine which alerts pharmacists to possible over-prescribing of acetaminophen.

References

1. Acetaminophen Prescription Products Limited to 325 mg Per Dosage Unit: Drug Safety Communication. FDA. 2011. 15 Jan 2011 <<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm239955.htm>>
2. First DataBank, accessed 1/14/11.

