

## FDA ANNOUNCEMENT: LIMITING THE MAXIMUM AMOUNT OF ACETAMINOPHEN

The U.S. Food and Drug Administration (FDA) is asking drug manufacturers to limit the strength of acetaminophen in prescription drug products, which are predominately combinations of acetaminophen and opioids. This action will limit the amount of acetaminophen in these products to 325mg per tablet, capsule, or other dosage unit, making these products safer for patients.

In addition, the following WARNINGS are being added to the label of all prescription drug products that contain acetaminophen:

- ◆ The potential for severe liver injury may occur
- ◆ The potential for allergic reactions may occur

**NOTE: OVER-THE-COUNTER (OTC) PRODUCTS CONTAINING ACETAMINOPHEN ARE NOT AFFECTED BY THIS ACTION.**

The maximum amount of acetaminophen in a prescription tablet, capsule, or other dosage unit will be limited to 325mg. However, the total number of tablets or capsules that may be prescribed, and the time intervals at which they may be prescribed, will not change as a result of the lower amount of acetaminophen. This is further explained by the following example:

- ◆ If a product that previously contained 500mg of acetaminophen with an opioid was prescribed as 1-2 tablets every 4-6 hours, the dosage instructions can remain unchanged once the product is reformulated to contain only 325mg of acetaminophen.

## LIST OF MARKETED ACETAMINOPHEN-CONTAINING BRAND PRODUCTS

BRAND NAME	GENERIC NAME	DOSAGE FORM	STRENGTH
Esgic-Plus	Acetaminophen/Butalbital/Caffeine	Tablet/Capsule/Oral	500mg/50mg/40mg
Anexsia	Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	500mg/5mg
Anexsia	Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	750mg/10mg
Anexsia 7.5/650	Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	650mg/7.5mg
Co-Gesic	Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	500mg/5mg
Lortab	Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	500mg/10mg
Lortab	Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	500mg/5mg
Vicodin	Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	500mg/5mg
Vicodin ES	Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	750mg/7.5mg
Vicodin HP	Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	660mg/10mg
Zydone	Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	400mg/10mg
Zydone	Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	400mg/5mg
Zydone	Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	400mg/7.5mg
Percocet	Acetaminophen/ Oxycodone HCl	Tablet/Oral	500mg/7.5mg
Percocet	Acetaminophen/ Oxycodone HCl	Tablet/Oral	650mg/10mg
Roxicet 5/500	Acetaminophen/ Oxycodone HCl	Tablet/Oral	500mg/5mg
Roxilox	Acetaminophen/ Oxycodone HCl	Capsule/Oral	500mg/5mg
Tylox	Acetaminophen/ Oxycodone HCl	Capsule/Oral	500mg/5mg
Talacen	Acetaminophen/Pentazocine HCl	Tablet/Oral	650mg/25mg base

## GENERIC ACETAMINOPHEN COMBINATIONS WITH NO CURRENT BRAND NAME

GENERIC NAME	DOSAGE FORM	STRENGTH
Acetaminophen/Caffeine/Dihydrocodone	Capsule/Oral	356.4mg/30mg/16mg
Acetaminophen/Caffeine/Dihydrocodone	Tablet/Oral	712.8mg/60mg/32mg
Acetaminophen/Codeine Phosphate	Tablet/Oral	650mg/30mg
Acetaminophen/Codeine Phosphate	Tablet/Oral	650mg/60mg
Acetaminophen/Hydrocodone Bitartrate	Oral Solution	500mg/15ml/10mg/15ml
Acetaminophen/Hydrocodone Bitartrate	Oral Solution	500mg/15ml/7.5mg/15ml
Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	500mg/7.5mg
Acetaminophen/Hydrocodone Bitartrate	Tablet/Oral	650mg/10mg
Acetaminophen/Oxycodone HCl	Tablet/Oral	400mg/2.5mg
Acetaminophen/Oxycodone HCl	Tablet/Oral	400mg/5mg
Acetaminophen/Oxycodone HCl	Tablet/Oral	400mg/7.5mg
Acetaminophen/Oxycodone HCl	Tablet/Oral	400mg/10mg
Acetaminophen/Oxycodone HCl	Tablet/Oral	500mg/10mg

## REMINDER

### OTC MEDICATIONS (WITHOUT A PRESCRIPTION) NO LONGER REIMBURSED FROM FLEXIBLE SPENDING ACCOUNTS

Effective January 1, 2011, over-the-counter (OTC) medications were no longer eligible for reimbursement from Flexible Spending Accounts (FSA) unless the patient has a prescription for the OTC item. This became applicable for all OTC purchases made after January 1, 2011, even though the money being spent was a carryover balance from 2010. The Internal Revenue Service (IRS) had previously ruled that such purchases could not be made with FSA cards at the point of sale (even if the patient had a prescription) because the online system could not verify that an actual prescription existed.

**NOTE: THIS NEW IRS RULING DOES NOT APPLY TO INSULIN PRODUCTS.**

To see the actual release, click here: [www.irs.gov/pub/irs-drop/n-11-05.pdf](http://www.irs.gov/pub/irs-drop/n-11-05.pdf)