



U.S. Food and Drug Administration

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Improving Patient's Awareness of Acetaminophen in Over-the Counter (OTC) and Prescription (Rx) Medicines: “APAP” OFF and Icon ON

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Developing Guidance on Naming, Labeling, and
Packaging Practices to Minimize Medication Errors

FDA Public Workshop – June 24, 2010

Acetaminophen:

Important Ingredient in OTC and Rx Medicines

- One of the most widely used and most important medicines in the United States.
- When used according to the label directions has well-established record of safety and efficacy.
- Although very rare in the context of its broad usage, overdose can be toxic and lead to acute liver failure.

FDA Advisory Committees Meeting. June 29-30 2009. OTC and Rx Acetaminophen-containing Medicines.
<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm143083.htm>

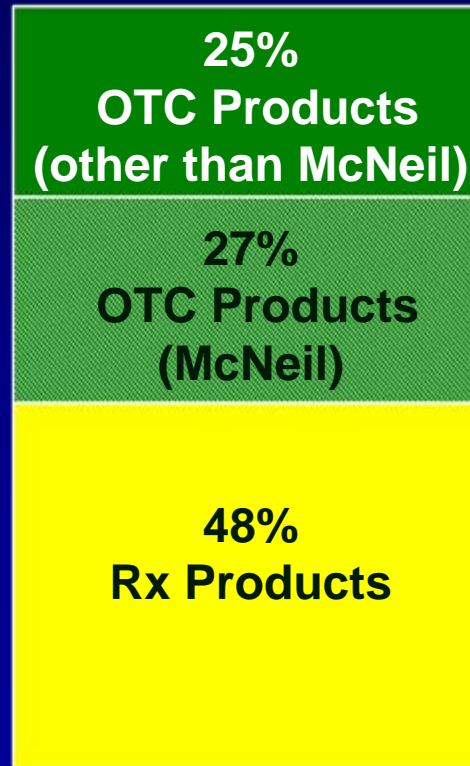
FDA Public Workshop: Medication Errors. June 24, 2010

Situation: Gaps in Acetaminophen Awareness

- Patients may not recognize that acetaminophen:
 - is the active ingredient
 - is common to many OTC and Rx medicines
 - use from multiple acetaminophen-containing products places them at risk for overdose
- Patients may not be able to identify acetaminophen in Rx medicines labeled as “APAP”
- Limited awareness has been identified as a root cause of medication errors leading to acetaminophen overdose
- Increasing patient understanding of acetaminophen and its proper use is key to minimizing risk

Increasing Acetaminophen Ingredient Awareness Needs to Involve Multiple Stakeholders

Acetaminophen products

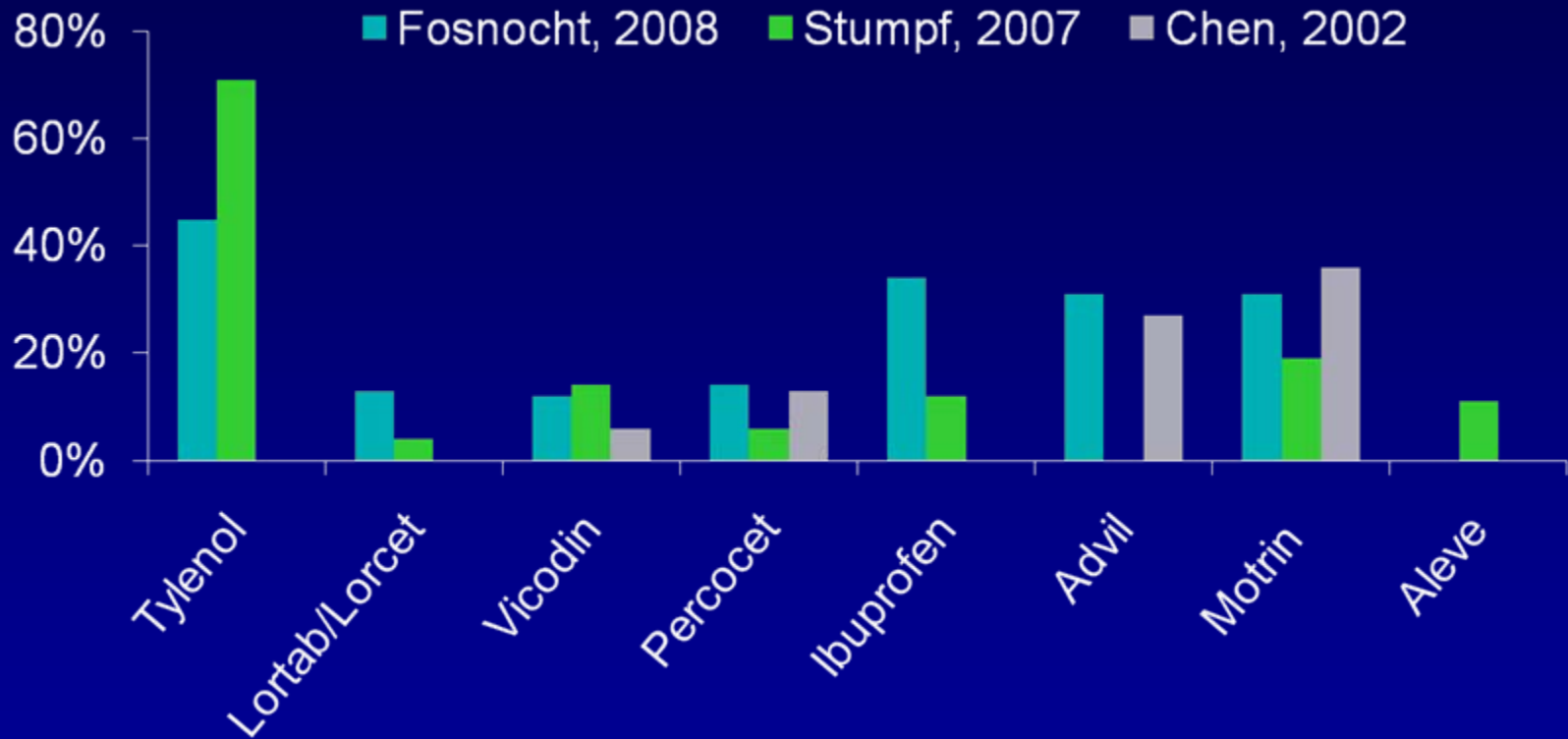


IMS Health, MIDAS May 2009; 24 billion Dosage Units of Acetaminophen Containing Medicines Sold (2008)

FDA Public Workshop: Medication Errors. June 24, 2010

Variable Awareness of Analgesic / Antipyretic Ingredients in OTC and Rx Products

Does this product contain acetaminophen? – “Yes”



1. Fosnocht D, Taylor JR, Caravati EM. Emergency department patient knowledge concerning acetaminophen (paracetamol) in over-the-counter and prescription analgesics. *Emerg. Med. J.* 2008;25:213-216
2. Stumpf JL, Skyles AJ, Alaniz C, et al. Knowledge of appropriate acetaminophen doses and potential toxicities in an adult clinical population. *Journal of the American Pharmacist Association.* 2007;47:1:35-41
3. Chen L, Schneider S, Wax P. Knowledge about acetaminophen toxicity among emergency department visitors. *Vet Human Toxicology.* 2002; 44: 370-373.

Many Patients Are Unaware that Rx Medicines Labeled as “APAP” Contain Acetaminophen

- Limited space in drug name fields in Rx drug name databases, pharmacy labeling systems and on the prescription container label, often prevent the use of complete generic drug names¹
 - If only a Rx brand name is used the label may not list acetaminophen or “APAP” at all¹
 - Acetaminophen is commonly abbreviated as “APAP” which patients may not recognize as acetaminophen^{1,2}
- Patients don’t recognize APAP as abbreviation for acetaminophen³

1. Institute for Safe Medicines Practices. “Pennsylvania State Board of Pharmacy Newsletter Winter 2007-2008 (page 4-5): “ Don’t Hide the Acetaminophen”
2. Letter from Steven Galson to State Boards of Pharmacy, Acetaminophen Hepatotoxicity and Nonsteroidal Anti-inflammatory Drug (NSAID)-related Gastrointestinal and Renal Toxicity (Jan 22, 2004) available at <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM171903.pdf>
3. Chen L, et al. Knowledge about acetaminophen toxicity among emergency department visitors. Vet Human Toxicology. 2002; 44: 370-373.

Recommendations to Help Patients Recognize Acetaminophen as an Ingredient in Rx Products

- Require only FDA-approved complete generic drug name in Rx drug name databases, pharmacy labeling systems, and on the pharmacy-generated prescription container label dispensed to patients
 - “Don’t Hide the Acetaminophen”¹
 - Spell out using complete drug name; avoid all abbreviations.²
 - Don’t use drug name abbreviations, such as APAP for acetaminophen, to avoid consumer confusion.³
 - Replace “APAP” with “acetaminophen”
- The complete name of “acetaminophen “ is already on OTC drug labels and principal display panel⁴

¹ Institute for Safe Medicines Practices. “Pennsylvania State Board of Pharmacy Newsletter Winter 2007-2008 “ Don’t Hide the Acetaminophen”

² USP Quality Review “Abbreviations Can Lead to Medication Errors” 2004;80:1-7

³ Letter: Steven Galson to State Boards of Pharmacy, Acetaminophen Hepatotoxicity and Non-steroidal Antiinflammatory Drug (NSAID)-related Gastrointestinal and Renal Toxicity (Jan 22, 2004) <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM171903.pdf>

⁴ FDA Organ Specific Warnings; OTC IAA Drug Products. 74 FR 19385 (April 29, 2009)

Innovative Ways to Improve Acetaminophen Awareness: Acetaminophen Icon Development¹

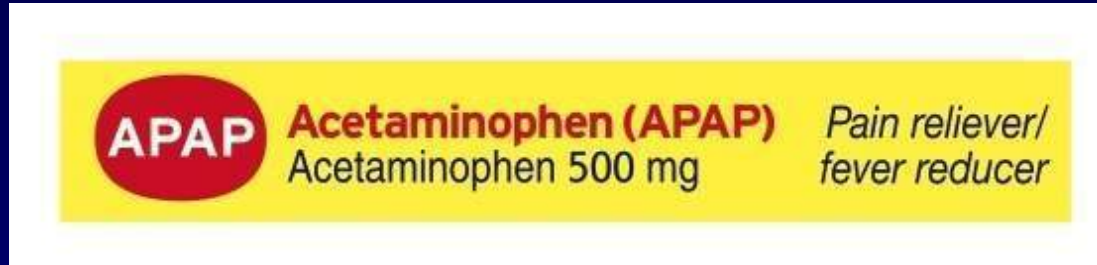
- Premise:
 - A graphical icon (symbol) may help consumers recognize acetaminophen in multiple products, and help minimize simultaneous use
- Goals:
 - Primary: Improve recognition and awareness of acetaminophen as an active ingredient
 - Secondary: Avoid use of multiple products containing acetaminophen at the same time
- Proposal: Add acetaminophen ingredient icon to all OTC & Rx acetaminophen-containing medicines¹

1. FDA Advisory Committee Meeting June 29-30, 2009 McNeil Consumer Healthcare: Acetaminophen Containing Medicines

Acetaminophen Icon Development: Lessons Learned From Qualitative Testing

- Icon (symbol) accompanied with OTC Drug Facts text is more effective than an icon alone
- Acetaminophen-icon supports recognizing the ingredient and warnings on OTC and Rx products
- Healthcare providers agree:
 - acetaminophen-icon is needed on both Rx and OTC products
 - education is necessary to maximize impact

“APAP” as an Ingredient Icon Did Not Qualitatively Test Well



- 27/30 (90%) responses negative feedback
 - “APAP” – confused about – have no idea what it means. Don’t know what it is.
 - Don’t know what “APAP” means – but doctor/pharmacist would understand. But I know what acetaminophen means

Increase Acetaminophen Ingredient Awareness:

Example of Icon across multiple adult acetaminophen containing products

Drug Facts

Active ingredient (in each caplet)

CONTAINS ACETAMINOPHEN

Acetaminophen 500 mg.....Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - the common cold
 - minor pain of arthritis
 - headache
 - toothache
 - backache
 - muscular aches
 - premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this



CONTAINS ACETAMINOPHEN

Drug Facts

Active ingredient (in each caplet)

CONTAINS ACETAMINOPHEN

Acetaminophen 325 mg.....Pain reliever
Phenylephrine HCl 5 mg.....Nasal decongestant

Uses

- for the temporary relief of:
 - headache
 - sinus congestion and pressure
 - nasal congestion
 - minor aches and pains
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 gelcaps in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using it



Drug Facts

Active ingredient (in each caplet)

CONTAINS ACETAMINOPHEN

Acetaminophen 500 mg.....Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - the common cold
 - minor pain of arthritis
 - headache
 - toothache
 - backache
 - muscular aches
 - premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this



Drug Facts

Active ingredient (in each caplet)

CONTAINS ACETAMINOPHEN

Acetaminophen 325 mg.....Pain reliever
Aspirin 250 mg.....Pain reliever
Caffeine 65 mg.....Pain reliever aid

Uses

- temporarily relieves minor aches and pains due to:
 - the common cold
 - minor pain of arthritis
 - headache
 - toothache
 - backache
 - muscular aches
 - premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Aspirin warning: Aspirin may cause a severe allergic reaction which may include

- hives
- facial swelling
- asthma (wheezing)
- stomach
- nausea
- vomiting
- diarrhea
- stomach pain
- stomach bleeding

Cellulite warning: The recommended dose of this product contains about 65 mg of caffeine.

Headache Relief



Family Pharmacy (555)321-4567
8234 MAPLE STREET
CLEVELAND, OH 44109

123456 04/26/2011 Dr. Alex Smith

JOHN DOE
TAKE 1 PILL WITH FOOD
TWICE DAILY

CONTAINS ACETAMINOPHEN

PERCOCET 20 DOSE Qty 20 pills

REFILL (2) TIMES AT 08 UNTIL 03/03/2012

May 1 CIA RPT 11/11/11 J00000000

Drug Facts

Active ingredient (in each caplet)

CONTAINS ACETAMINOPHEN

Acetaminophen 500 mg.....Pain reliever/fever reducer
Dextromethorphan HBr 15 mg.....Cough Suppressant
Doxylamine succinate 6.25 mg.....Antihistamine

Uses

- temporarily relieves cold/flu symptoms:
 - cough due to minor throat and bronchial irritation
 - sore throat
 - fever
 - headache
 - minor aches and pains
 - runny nose and sneezing

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Store Throat Warning: If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, seek medical attention promptly.



Note: for demonstration purposes only. Manufacturers beyond McNeil have not been consulted

Recommendations to Allow Icons and Pictograms in the Context of OTC Drug Facts Labeling

- FDA allows use of highlighting (fluorescent or color contrast) or bold type to increase prominence of OTC IAAA ingredients¹. OTC Drug Facts does not allow graphical images/pictograms to appear within Drug Facts labeling²
- Encourage FDA to allow uniform graphical images such as icons (symbols) and pictograms as an additional option within OTC Drug Facts
 - to increase prominence and recognition
 - to aid navigation, clarify and highlight certain aspects of the text
 - but not to replace the actual text
- Encourage FDA to recognize and endorse standard procedures for testing of effectiveness for symbols (i.e. American National Standards Institute³)

1. FDA Organ Specific Warnings; OTC IAAA Drug Products. 74 FR 19385 (April 29, 2009)

2. OTC Drug Product Labeling. FR 64 Part 201.66 13286 March 17, 1999

3. American National Standard Criteria for Safety Symbols (ANSI Z535.3) – Procedures for Evaluating Image Effectiveness and Considerations for Graphic Design.