

Simple patient reminders for all medication use

- Always read and follow the label
- Never exceed the recommended dose
- Never take more than one medication with the same active ingredient at the same time

Patient education resources can be downloaded or ordered at **TylenolProfessional.com**

◀ ***Please see new
Extra Strength
TYLENOL® dosing
instructions inside***

New Dosing Instructions for Extra Strength **TYLENOL**® Products

The revised dosing instructions on the OTC label for Extra Strength **TYLENOL**® reflect the following changes:

- **take 2 caplets (1,000 mg) every 6 hours while symptoms last**
(revised from 2 caplets every 4 to 6 hours)
- **not to take more than 6 caplets (3,000 mg) in 24 hours, unless directed by a doctor**
(revised from 8 caplets in 24 hours)
- The Warnings section will be modified to reflect the new daily dose
 - Specifically, the liver warning on the OTC label will continue to state that severe liver damage may occur if more than 4,000 mg of acetaminophen is taken

Current Directions

EXTRA STRENGTH **TYLENOL**® (500 mg per caplet)

Directions

- do not take more than directed (see overdose warning)

adults and
children 12
years and over

- take 2 caplets every 4 to 6 hours as needed
- do not take more than 8 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor

children under
12 years

do not use this Extra Strength product in children under 12 years of age; this will provide more than the recommended dose (overdose) of **TYLENOL**® and may cause liver damage

Revised Directions

EXTRA STRENGTH **TYLENOL**® (500 mg per caplet)

Directions

- do not take more than directed (see overdose warning)

adults and
children 12
years and over

- take 2 caplets every 6 hours while symptoms last
- do not take more than 6 caplets in 24 hours, unless directed by a doctor
- do not use for more than 10 days unless directed by a doctor

children under
12 years

ask a doctor

For patients whose pain or fever recurs despite the administration of a total daily dose of 3,000 mg, the new dosing instructions allow for healthcare professionals to exercise their discretion.

Remind patients

- always read and follow the label
- never exceed the recommended dose
- never take more than one acetaminophen-containing medication at the same time

Reassure patients

- they can continue to use their current **TYLENOL**® products, including **TYLENOL**® products on store shelves, as currently labeled

Reinforce

- **TYLENOL**® is an excellent first-line analgesic for many of your patients. When used as directed, **TYLENOL**® provides both analgesic efficacy and an exceptional safety profile



Use only as directed.

The new dosing instructions will appear on Extra Strength **TYLENOL**® product packages beginning this fall. Your patients can continue to use their Extra Strength **TYLENOL**® products as currently labeled as this change is not being implemented because of any safety concerns inherent with the product or current labeling.

Frequently Asked Questions

New Dosing Instructions

1 What are the new dosing instructions for Extra Strength TYLENOL®?

The new dosing instructions will lower the maximum daily dose for single-ingredient Extra Strength TYLENOL® (acetaminophen) products sold in the U.S. from 8 pills per day (4,000 mg) to 6 pills per day (3,000 mg). The new dosing instructions will also change the dosing interval from every 4 to 6 hours to every 6 hours. McNeil Consumer Healthcare is working closely with other manufacturers of acetaminophen-containing products to help ensure consistency in dosing instructions.

2 Why are you changing the label instructions for TYLENOL® and other adult acetaminophen-containing products?

McNeil Consumer Healthcare is voluntarily implementing new measures, including the label change, that are designed to help lessen the possibility of accidental acetaminophen overdose and help encourage people who use TYLENOL®, and other adult acetaminophen-containing products, to use them appropriately.

3 Will store brand and generic acetaminophen dosing instructions change as well?

McNeil Consumer Healthcare is working closely with other manufacturers of acetaminophen products to help ensure consistency in dosing instructions.

Safety and Efficacy

4 Are there data showing the efficacy of 1,000 mg of acetaminophen at 6-hour dosing intervals?

Yes. 1,000 mg has been demonstrated to provide effective relief at 6 hours.

5 Can I still recommend 4,000 mg per day of Extra Strength TYLENOL® to patients?

When recommending Extra Strength TYLENOL®, it is important to discuss the new OTC label with patients, specifically the new 6-hour dosing interval and 3,000 mg total daily dose. Healthcare providers can help prevent overdose and liver injury by reinforcing the importance of reading and following the OTC label.

For patients whose pain or fever recurs despite the administration of a total daily dose of 3,000 mg, the new dosing instructions allow for healthcare professionals to exercise their discretion. The efficacy and safety of TYLENOL® products at the maximum daily dose of 4,000 mg per day have been well established in clinical studies and actual use. Patients should be instructed not to take more than 3,000 mg per day unless under the direction of a healthcare provider.

Other TYLENOL® Products

6 What are the new dosing instructions for Regular Strength TYLENOL®?

Changes to the dosing instructions for Regular Strength TYLENOL® (acetaminophen) will take place in the upcoming year. McNeil Consumer Healthcare will be voluntarily lowering the maximum daily dose of Regular Strength TYLENOL® products sold in the U.S. from 12 pills per day (3,900 mg) to 10 pills per day (3,250 mg).

7 What are the new dosing instructions for the other adult acetaminophen-containing OTC products?

McNeil will be revising the dosing instructions for other adult acetaminophen-containing OTC products and multi-ingredient/upper respiratory OTC products in 2012. The maximum daily dose of other adult acetaminophen-containing OTC products sold in the U.S. by McNeil with 325 mg of acetaminophen per tablet or other dosage unit will be lowered to 3,250 mg. There are no plans to change the labeling for TYLENOL® Arthritis Pain or TYLENOL® 8 Hour at this time, and TYLENOL® PM is already labeled for a maximum daily dose of 1,000 mg of acetaminophen.

Additional Questions

8 What should consumers who have purchased TYLENOL® products with the old label do with those products?

Consumers can continue to use their current TYLENOL® products, including TYLENOL® products on store shelves, as labeled. This change is not being implemented because of any safety concerns inherent with the product or current labeling. TYLENOL® remains the brand of pain reliever that doctors recommend more than any other and that hospitals use most.

9 Are the changes made to Extra Strength TYLENOL® related to the FDA's announcement limiting the amount of acetaminophen in prescription combination products?

No. The U.S. Food and Drug Administration's (FDA) January 2011 announcement pertained specifically to prescription medications containing acetaminophen. There were no required formulation or label changes for over-the-counter (OTC) medicines containing acetaminophen. McNeil Consumer Healthcare is voluntarily implementing these changes to help ensure that people who use TYLENOL® products use them appropriately.