

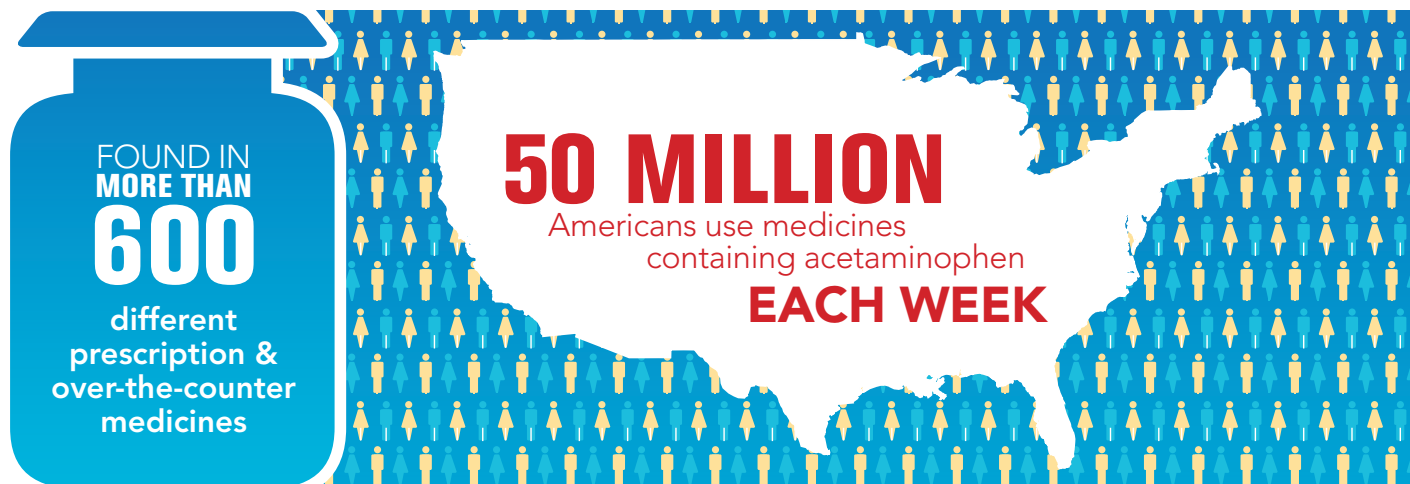


ACETAMINOPHEN:

How It's Used,
Preventing Overdose and
What We Can Do to
Promote Safe Use

ACETAMINOPHEN

THE MOST COMMON DRUG INGREDIENT IN AMERICA



USING IT



Acetaminophen is a **safe and effective pain reliever and fever reducer** when used as directed. More than 95% of the time, it is taken according to directions on the medicine label.¹



AVOIDING OVERDOSE

EXCEEDING THE MAXIMUM DAILY DOSE



of 4,000 mg is an overdose and can lead to liver damage²

OF THOSE WHO EXCEED 4,000 MG IN 1 DAY, MOST DO SO BY³



Taking the next dose too soon



Using multiple products containing acetaminophen



Taking too much at one time



PROMOTING SAFE USE & EDUCATING CONSUMERS

EDUCATION IS WORKING

More consumers are aware that "exceeding the recommended dose can lead to liver damage"⁴

78%
2010

87%
2013

FOLLOW SAFE USE STEPS

1. Always read & follow the medicine label
2. Know if your medicines contain acetaminophen
3. Never take two acetaminophen-containing medicines at the same time
4. Ask your healthcare professional or pharmacist if you have questions

1. <http://www.ncbi.nlm.nih.gov/pubmed/23001694>

2. <http://onlinelibrary.wiley.com/doi/10.1002/hep.20948/pdf>

3. "Acetaminophen Use Patterns" Presentation. https://www.pharmacoepi.org/meetings/28ICPE/presentations/aj_oral_presentations_key.cfm

4. <http://www.chpa.org/Templates/PressRelease.aspx?id=2717>

ACETAMINOPHEN

How It's Used, Preventing Overdose and What We Can Do to Promote Safe Use

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EXECUTIVE SUMMARY

Every day, millions of Americans rely on medicines to improve or maintain their health. One of the most commonly used drug ingredients in the United States is acetaminophen, a pain reliever and fever reducer found in more than 600 different over-the-counter and prescription medicines.¹ More than 50 million Americans use an acetaminophen-containing medicine each week to treat pain, fever, and aches and pains associated with cold and flu symptoms.² For some consumers, including older adults with persistent pain, patients with stomach conditions such as ulcers and pregnant women, acetaminophen is the best or only option for pain relief. This makes it critically important that we understand how acetaminophen is used, how it's sometimes inappropriately used and overdosed, and what can be done to promote safer use.

Acetaminophen has long been proven to be safe and effective when taken as directed, but there is a limit to how much should be taken in one day: 4,000 milligrams (mg). Taking more than directed is an overdose and can lead to severe liver damage. Though total instances are rare in the context of the ingredient's widespread use, acetaminophen overdose is the leading cause of acute liver failure in the United States.³ While the majority of these overdose-related liver failure cases are intentional (i.e., suicide or suicide attempt), nearly half are associated with unintentional overdoses—people accidentally exceeding the total 4,000 mg daily dose by not reading or following dosing instructions and taking multiple acetaminophen-containing medicines at the same time, taking too much at one time, and/or redosing too soon. For this reason, education is essential to ensuring appropriate use.

In 2010, a group of leading health and consumer organizations and healthcare professionals came together to form the Acetaminophen Awareness Coalition (AAC). The Coalition's objective is to educate consumers on the importance of knowing the ingredients in their medicines and following labeled directions to prevent inappropriate acetaminophen use and unintentional acetaminophen overdose. In 2011, the AAC launched a public education campaign called *Know Your Dose* to reach consumers, patients and healthcare professionals with safe use education, information and resources.

This report is a compilation of some recent research on acetaminophen that explores adult use; how it may be inappropriately used or unintentionally overdosed; and what healthcare professionals, drug manufacturers, health advocates, regulators, consumers, media and other stakeholder groups have accomplished together to promote its safe use. Though uncommon, liver damage related to acetaminophen overdose is serious. Reducing liver injuries begins with understanding the problem and risk factors, then developing and implementing solutions targeted to those risk factors. New research on the dosing behaviors and risk factors associated with exceeding the total 4,000 mg daily dose of acetaminophen, as well as on the effectiveness of acetaminophen safe use education, will inform these solutions. Reinforcing the need for everyone who uses acetaminophen-containing medicines to take them safely is essential, as is emphasizing the importance of reading and following medicine labels. Coordinated, comprehensive and robust educational initiatives—described in this report—have been put in place in recent years to promote safe use across multiple channels and via multiple stakeholders collaborating together. The AAC urges continued collaboration and education to further spread the word about the importance of using acetaminophen appropriately.



50 MILLION

Americans use acetaminophen each week.

This is the equivalent of:

5,000 PEOPLE PER MINUTE.

COMMON MEDICINES* THAT MAY CONTAIN ACETAMINOPHEN:

Over-the-Counter

Alka-Seltzer Plus®
Contac®
Coricidin® HBP
Dimetapp®
Excedrin®
Midol®
Mucinex®
Nyquil®/Dayquil®
Robitussin®
Sudafed®
Theraflu®
Triaminic®
Tylenol®

Prescription

Butalbital
Endocet®
Fioricet®
Hycotab
Hydrocet®
Hydrocodone
Lortab®
Oxycodone
Percocet®
Phenaphen®
Sedapap®
Tramadol®
Tylenol® w/ Codeine
Ultracet®
Vicodin®

* Acetaminophen is also contained in the generic and store brands of these medicines.

NOTE: This list is just a sample of the more than 600 different medicines that contain acetaminophen.

1) WHAT IS ACETAMINOPHEN?

Acetaminophen (pronounced: a-seet-a-MIN-o-fen), also known in other parts of the world as paracetamol (para-SEET-a-mol), is a widely used fever reducer and pain reliever that temporarily relieves minor aches and pains, such as those due to the common cold, headache, backache, minor pain of arthritis, toothache, muscular aches, and premenstrual and menstrual cramps. It is the most commonly used drug ingredient in America. More than 50 years of consumer use and scientific investigation has established acetaminophen as safe and effective when used as directed at recommended doses. However, like any medicine, there is a limit to how much should be taken in one day. For acetaminophen, the maximum daily dose is 4,000 milligrams (mg).⁴

Single-Ingredient and Combination Medicines Containing Acetaminophen

Acetaminophen is a generic name. There are more than 600 medicines that contain acetaminophen, including over-the-counter (OTC) medicine brands such as Excedrin®, Midol®, Mucinex® Sinus Max, Nyquil®, Robitussin®, Sudafed®, Triaminic® and Tylenol®, and prescription medicines like Endocet®, Percocet® and Vicodin®. Sometimes, acetaminophen is the only active drug ingredient in a medicine. These are "single-ingredient" medicines, like Regular Strength Tylenol® and Extra Strength Tylenol®. Acetaminophen can also be found in many products with more than one active ingredient ("combination medicines"), such as Vicks® Nyquil Severe Cold or Percocet®. These may also be sold under generic or store brand names.

Drug Facts

Active ingredient (in each tablet)	Purpose
Acetaminophen XXX mg.....	Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - the common cold
 - headache
 - backache
 - minor pain of arthritis
 - toothache
 - 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 X tablets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Acetaminophen is in
MORE THAN 600
over-the-counter and
prescription medicines



If acetaminophen is in an OTC medicine, it will be listed on the product package and on the label. Acetaminophen is always prominently written on the front of the box or packaging and will often be highlighted or bolded in the active ingredients section of the “Drug Facts” label.

Acetaminophen has been commonly identified on prescription labels as “APAP,” “acetam” or other abbreviated versions of the word. Recognizing the potential for confusion, the pharmacy standards development organization National Council for Prescription Drug Programs (NCPDP) initiated a task group of government, industry, and professional and consumer advocacy organizations to encourage pharmacies to spell out “acetaminophen” in full on prescription drug labels. This effort is aimed at eliminating the potential for consumer confusion caused by the use of abbreviations.



Acetaminophen Dosing

The amount of acetaminophen in an individual product is included on the medicine label and is measured in milligrams (mg). **The maximum daily limit is 4,000 mg of acetaminophen per day for adult use.**⁵ For some populations, such as people with underlying liver disease or those who drink three or more alcoholic beverages every day, the daily limit, or the maximum amount that can be safely taken in one day, may be less and should be discussed with a healthcare professional.

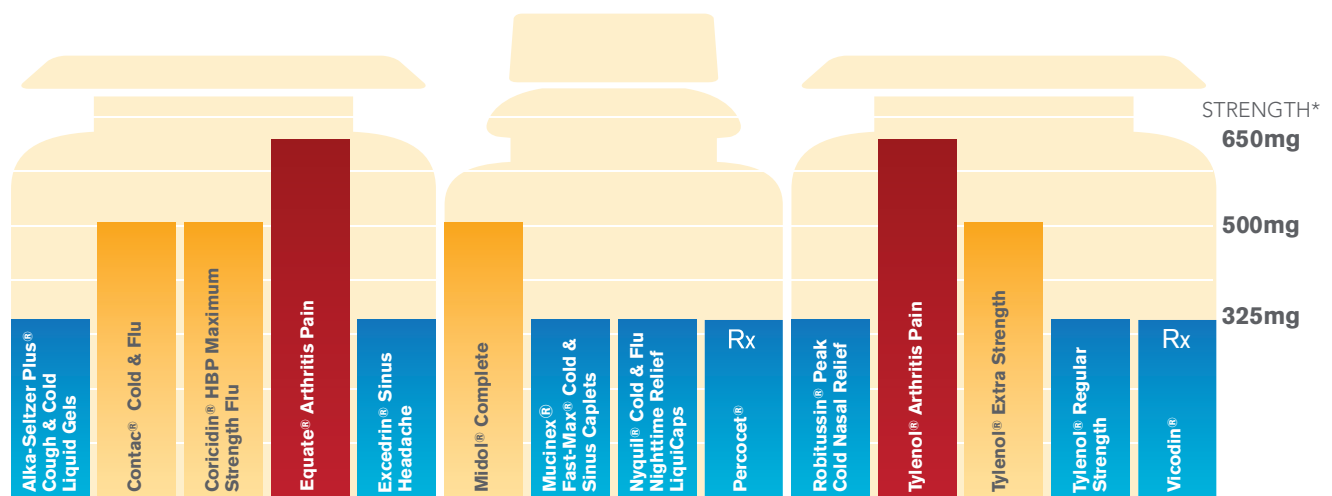
The amount of acetaminophen in an OTC medicine is stated in the active ingredients section of the “Drug Facts” label. Most OTC medicines for adults that contain acetaminophen have one of the following three strengths:

- 325 mg per tablet/capsule or liquid dose: “regular strength”
- 500 mg per tablet/capsule or liquid dose: “extra strength”
- 650 mg per tablet/capsule: “extended relief”

For acetaminophen-containing prescription combination medicines such as Percocet[®] and Vicodin[®], the amount of acetaminophen is now limited to 325 mg per tablet/capsule, following a request made by the U.S. Food and Drug Administration (FDA) to manufacturers to lower the dose of acetaminophen in these medicines. Prior to this change, many prescription opioid medicines contained unit doses of acetaminophen of 500 mg or higher. Limiting the amount of acetaminophen per dosage unit of these prescription combination medicines is expected to help reduce the risk of severe liver injury from inadvertent acetaminophen overdose.⁶ Prior to this change, studies had shown that the majority (63 percent) of patients who suffered acute liver failure following an unintentional overdose of acetaminophen had been taking prescription narcotic-acetaminophen combination pain medicines.⁷

With different strengths of acetaminophen across many different types of medicine, it is critical to read and follow medicine labels to understand dosage strength and unique dosing directions for each product and to avoid taking multiple acetaminophen-containing medicines at the same time.

ACETAMINOPHEN IN YOUR OVER-THE-COUNTER AND PRESCRIPTION MEDICINES: KNOW YOUR MILLIGRAMS



NOTE: This information also applies to the generic/store brand versions of these products. Medicines that come in generic form may list the ingredients in place of a drug name. Always read and follow the Drug Facts label, and ask your pharmacist or healthcare provider if you have questions about the ingredients in your medicine.

Acetaminophen in milligrams (mg).

*Based on one tablet, capsule, caplet or gel cap.

SOURCE: Drug Facts label.



Acetaminophen and Liver Damage

Taking more acetaminophen than directed and exceeding the maximum daily dose of 4,000 mg is considered an overdose and can lead to severe liver damage.⁸

Like many drugs, acetaminophen is metabolized in the liver, which is an essential organ that filters the blood coming from the digestive tract before passing it to the rest of the body. Most acetaminophen gets broken down in the liver and altered into harmless substances that are excreted in the urine. A small percentage is converted into a compound known as NAPQI that can be harmful to liver cells in large amounts. Ordinarily, this compound is rendered harmless (detoxified) as part of the body's natural processes. However, if the NAPQI compound builds up in the body stemming from acetaminophen overdose and is not detoxified, it can cause rare but serious side effects, result in liver damage or liver failure (i.e., the rapid loss of liver function), or even lead to death.

The percent of overall acetaminophen users who exceed the maximum labeled dose when using the medicine is very low, and in the vast majority of instances it does not result in side effects or adverse events such as liver damage. Nonetheless, acetaminophen overdose is the leading cause of acute liver failure (ALF), and is estimated to be responsible for nearly half of all ALF cases.⁹ Acute liver failure is rare in the United States, with an estimated 2,000 cases per year. According to the U.S. Liver Failure Study Group, a consortium of investigators and clinical centers that consolidate data, acetaminophen-related ALF results in roughly 450 deaths each year.¹⁰ It is important to note that the number of deaths is due primarily to intentional overdose of acetaminophen (suicide or attempted self-harm), while accidental or unintentional overdose is linked to an estimated 100-150 deaths each year.¹¹



**ACETAMINOPHEN
OVERDOSE**
drives an estimated
26,000
hospitalizations
per year



2,240
of which are
associated with
unintentional
overdose

Overall acetaminophen overdose is associated with an estimated 56,000 emergency room visits and 26,000 hospitalizations in the United States annually. These numbers include both intentional overdoses (estimated at 43,350 emergency room visits and 23,760 hospitalizations per year) and unintentional overdoses (estimated at 12,650 emergency room visits and 2,240 hospitalizations per year) from both adult and pediatric patients. Pediatric overdose drove 17 percent of emergency room visits and is primarily driven by “unsupervised accidental ingestion”—young children getting into medicine left within reach.¹² This is best prevented by storing all medicines up and away and out of sight and reach of children. As this report specifically focuses on adult use and misuse of acetaminophen, please visit www.KnowYourDose.org for additional information on acetaminophen use in children or consult the dosing chart on p. 24.

While intentional overdose (suicide, attempted self-harm) drives the significant majority of ER visits and hospitalizations, unintentional overdose is associated with nearly half of all acute liver failure cases. This is thought to be because people intending suicidal harm ingest a large amount of acetaminophen at one time, but then can quickly call for help—or help can be called for them—and they are able to get to the emergency room for immediate treatment. With unintentional overdose, patients are often less likely to realize that the early liver damage symptoms (commonly nausea, vomiting, sweating, loss of appetite, diarrhea) they are feeling may be associated with liver damage rather than with the health condition they were already treating, and so are less likely to seek immediate care after symptom onset. As a result, when they arrive at the emergency room days later, they tend to have more advanced liver damage.¹³ Enabling consumers to prevent unintentional overdose via coordinated and comprehensive safe use education is paramount.

2. UNINTENTIONAL ACETAMINOPHEN OVERDOSE: Factors Associated With Exceeding the Maximum Labeled Dose

An estimated 50 million Americans use acetaminophen each week to treat conditions such as pain, fever and aches associated with cold and flu, arthritis, and other common ailments. The overwhelming majority of times—more than 95 percent of the time according to research—acetaminophen is taken safely, appropriately and according to the directions on the medicine labels.¹⁴ However, there continue to be consumers who intentionally (suicide attempt) and unintentionally take too much. This section explores some of the research into how unintentional acetaminophen overdoses can occur and who is most at risk.

A recent study that looked at patterns of therapeutic acetaminophen use by U.S. adults showed that for that 4.5 percent of consumers who did exceed the maximum labeled dose of 4,000 mg per day, there were three common underlying dosing patterns:

1. Taking the next dose too soon (72 percent of those who exceeded 4,000 mg/day)
2. Using multiple products that contain acetaminophen (59 percent of those who exceeded 4,000 mg/day); and/or
3. Taking too much at one time (34 percent of those who exceeded 4,000 mg/day)¹⁵

Taking too much at one time and taking the next dose too soon are often associated with consumers struggling to manage their pain. Using multiple products that contain acetaminophen (“doubling up”) can occur in different scenarios when patients do not realize their medicines contain acetaminophen or they do not read and follow the label. This can include taking multiple acetaminophen-containing OTC medicines (a pain medicine with a cold medicine, for example), multiple acetaminophen-containing prescription pain medicines, or a combination of both an acetaminophen-containing prescription and an OTC medicine (a prescription pain medication with a cold medicine, for example).¹⁶

EXCEEDING THE LABELED DOSE: COMMON ACETAMINOPHEN DOSING MISTAKES



Taking the next dose **too soon**



Using multiple acetaminophen-containing products at the same time



Taking more than the recommended dose at a single time

CONSUMER MISCONCEPTIONS CAN CONTRIBUTE TO MISUSE

"The root causes of therapeutic errors and misuse of over-the-counter medicines are attributable to inaccurate attitudes and wrong beliefs."

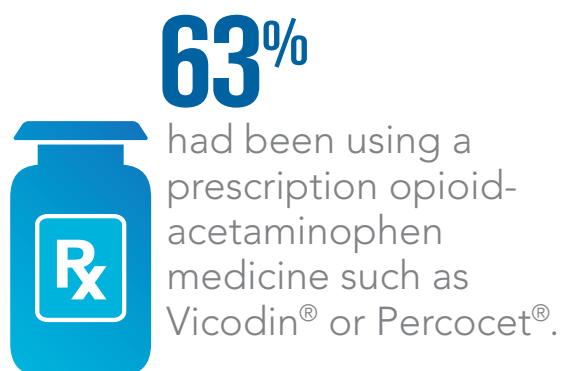
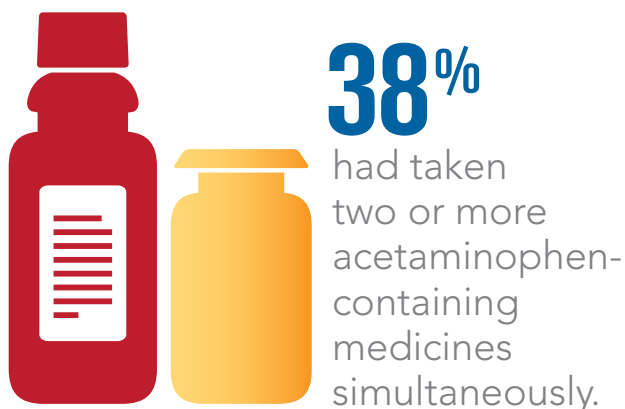
- An **American College of Preventive Medicine** 2011 report shows that adults sometimes intentionally take more than the recommended dose of a medicine based on the misconception that it would bring relief more quickly or would help with severe symptoms.²⁰

Using Multiple Acetaminophen-Containing Products at the Same Time

The concurrent use of multiple medicines—both prescription and OTC—to manage coexisting chronic conditions is an increasingly common occurrence. According to the Institute of Medicine, in any given week, four out of every five U.S. adults will use prescription medicines, OTC drugs or dietary supplements; and nearly one-third of all adults will take five or more different medications each day.¹⁷ This concomitant use—using more than one medicine at the same time—can be appropriate and safe when medicines do not contain the same active ingredient and have no drug-drug interactions. But when two medicines with the same active ingredient are taken at the same time—such as taking a prescription medicine for pain along with an OTC cold medicine, both of which likely contain acetaminophen—it can result in an unintentional overdose.

Research illustrates that taking multiple acetaminophen-containing medicines at the same time is a risk factor for acetaminophen overdose. Consumers were 4.5 times more likely to exceed the 4,000 mg maximum daily dose on days when both OTC and prescription acetaminophen-containing medicines were taken.¹⁸ Similarly, a study at 22 hospital centers showed that of patients who suffered acute liver failure (ALF) following an unintentional overdose of acetaminophen, 38 percent had taken two or more acetaminophen-containing medicines simultaneously, and 63 percent had used prescription opioid-acetaminophen combination pain medicines such as Vicodin[®] and Percocet[®].¹⁹

In a study of patients who suffered acute liver failure after unintentional acetaminophen overdose,





Acetaminophen Overdose and Chronic Pain

A recent medicine “diary” study asked 5,649 adults to record all medicines they took over the course of a week. Of the more than 3,600 adults who took acetaminophen-containing products, 95.5 percent did not exceed the 4,000 mg maximum daily dose of acetaminophen, while 4.5 percent exceeded that maximum daily dose. Virtually all acetaminophen users in the study who exceeded the 4,000 mg maximum daily dose reported having some ongoing pain during the diary period, with 64 percent reporting it had lasted at least six months (i.e., chronic pain).²¹

“Impulsive Overdosing” for Pain

The U.S. Acute Liver Failure Study Group looked in its database for cases of unintentional acetaminophen overdose contributing to liver failure and found that 15 percent involved patients not realizing they were taking multiple acetaminophen-containing medicines at the same time. The more common reason for liver failure due to unintentional acetaminophen overdose was “impulsive overdosing.”²² This occurs when patients do not feel relief from their pain in a timely manner and consume large amounts of acetaminophen-containing medicines chronically over several days, often without realizing the risks.

It can be the sense of inadequate pain management that drives a consumer to re-dose sooner than the medicine label instructs, to take too much medicine or to take pain medications chronically over a long period of time. Knowing which pain conditions are associated with impulsive overdosing is critical to targeting educational messages to the users most at risk. The most common pain conditions mentioned in the research were chronic back pain and headache. Fibromyalgia, rheumatologic pain, orthopedic pain and toothache were also noted as reasons for taking acetaminophen when its overdose was associated with liver failure.²³

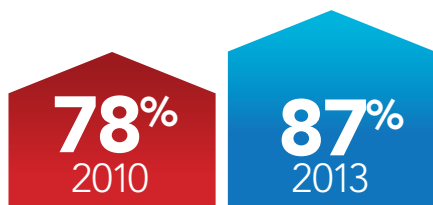
People living with and treating pain are encouraged to have an ongoing dialogue with their healthcare provider to find a pain management solution that is safe and appropriate. Reduced pain can often be achieved by adjustments in medication regimen or dosage strength, as well as other non-medicine alternatives like meditation and stretching—under the guidance of a healthcare professional.

COMMON PAIN CONDITIONS ASSOCIATED WITH “IMPULSIVE OVERDOSING”

chronic back pain
headache
fibromyalgia
rheumatologic pain
orthopedic pain
toothache

EDUCATION IS WORKING

More consumers are aware that “exceeding the recommended dose can lead to liver damage.”



3. PROMOTING SAFE USE THROUGH CONSUMER EDUCATION

Research shows that adults with knowledge of the ingredients in their medicines and the appropriate dose have a lower likelihood of exceeding the maximum daily dose of 4,000 mg of acetaminophen.²⁴ As such, education that focuses on increasing ingredient knowledge and addressing the dosing patterns that underlie exceeding labeled directions when it does occur—such as using multiple products with acetaminophen at the same time, taking more than the recommended dose at one time and re-dosing too soon—is key to preventing unintentional acetaminophen overdose and the rare but concerning liver failure that can result. A number of ongoing national education campaigns are focused on increasing consumer awareness about acetaminophen, its risks, and how to use it appropriately and within the recommended daily dose.

Over the last three years, acetaminophen safe use messages from these efforts have been seen by consumers more than one billion times.

Education campaigns are having an impact on consumer knowledge of acetaminophen safe use. When it comes to treating pain, current research indicates that more consumers report knowing how to safely use medicines with acetaminophen and avoid accidental overdose and liver damage. A nationwide survey of 2,000 U.S. adult pain medicine users shows that safe use knowledge and risk awareness has increased over a three-year period (2010-2013):²⁵

- ▶ *Label reading:* The number of consumers who agree that it is “important to check the label to find out the maximum daily dose” of medicines increased from 93 percent in 2010 to 98 percent in 2013.
- ▶ *Following dosing instructions:* The number of consumers who agree it is “important not to exceed the dosing directions on the label” of pain relievers increased from 90 percent in 2010 to 96 percent in 2013.
- ▶ *Awareness of risk:* The number of consumers who understand that “exceeding the recommended daily dose of acetaminophen may lead to liver damage” increased from 78 percent in 2010 to 87 percent in 2013.
- ▶ *Avoidance of “doubling up:”* Knowledge that “acetaminophen can be found in many over-the-counter and prescription pain medicines” increased from 80 percent in 2010 to 87 percent in 2013, and understanding that “it is possible to exceed the maximum daily dose when taking an OTC acetaminophen product at the same time as a prescription pain medicine” increased from 76 percent in 2010 to 81 percent in 2013.

The *Know Your Dose* Campaign

In 2010, leading healthcare provider and pharmacy organizations came together with consumer and public health advocates to form the Acetaminophen Awareness Coalition. The Coalition includes the Alliance for Aging Research, American Association of Nurse Practitioners, American Academy of Physician Assistants, American Pharmacists Association, Consumer Healthcare Products Association Educational Foundation, National Association of Boards of Pharmacy, National Association of Chain Drug Stores Foundation, National Community Pharmacists Association, National Consumers League, and National Council on Patient Information and Education. The Centers for Disease Control and Prevention, U.S. Food and Drug Administration and American Academy of Pediatrics serve as advisors to the Coalition.

Through outreach and engagement with healthcare professional organizations, the Coalition encourages healthcare providers to counsel patients about safe use of acetaminophen, and reaches consumers directly with English and Spanish-language educational resources focused on safe use.





In 2011, the Coalition launched the *Know Your Dose* campaign to educate consumers on how to safely and appropriately use medicines that contain acetaminophen to avoid an unintentional overdose. Importantly, the *Know Your Dose* campaign is grounded in research and data—the messages, materials and targeting are based on qualitative and quantitative research with consumers and healthcare providers. This research established a baseline understanding of consumer awareness and perceptions surrounding acetaminophen and the behaviors that drive unintentional overdose. Research also validated the messaging and collateral elements to affirm that target audiences understand and are motivated to act on the communications. Further, through research the Coalition has assurances that the campaign communications appropriately alert consumers to the importance of safe use without undermining confidence in the safety and effectiveness of the ingredient when used appropriately.

The *Know Your Dose* campaign reaches consumers when medicine safety is contextually relevant and more likely to be top of mind: at points-of-care in health clinics and healthcare provider offices; at points-of-purchase in retail pharmacies; and at points-of-health information seeking when consumers are using popular media, websites and online searches for health content. The campaign informs consumers about the hundreds of medicines that contain acetaminophen and promotes four key steps for safe acetaminophen use:

1. Always read and follow the medicine label
2. Know if your medicines contain acetaminophen
3. Never take two acetaminophen-containing medicines at the same time
4. Ask your healthcare professional or pharmacist if you have questions



ACETAMINOPHEN SAFE USE TIPS

-  Always read and follow the medicine label
-  Know if your medicines contain acetaminophen
-  Never take two acetaminophen-containing medicines at the same time
-  Ask your healthcare professional or pharmacist if you have questions

Know Your Dose has generated more than 300 million educational media impressions reaching consumers across a range of channels, including its website KnowYourDose.org, which offers interactive resources including a helpful medicine label reader and a “Game of Life” educational quiz to help increase consumer acetaminophen awareness.

Partnership activity with the *Know Your Dose* campaign has included material distribution to retail pharmacies such as Costco, along with Walmart and Sam’s Club, which have also displayed posters, brochures and “shelf-talkers” throughout over-the-counter medicine aisles across their national network of stores. Additional retail efforts have included educational information attached to pick-up bags for acetaminophen-containing prescriptions, as well as education targeted to purchasers of OTC acetaminophen medicines via education printed with in-store purchase receipts. These retail engagements have exposed millions of consumers to highly targeted educational information during the purchase of prescription or over-the-counter medicines containing acetaminophen.

Through a partnership with the National Alliance for Hispanic Health, Spanish-language materials have been distributed to more than 250 community health clinics and community health fairs. Safe use educational content has also been highlighted in popular online and print media outlets such as WebMD and *PARADE* magazine, and within targeted chronic pain community sites such as Arthritis Connect, Pain Pathways and WarOnHeadaches.com. Importantly, more than 30 aligned health and consumer organizations have adopted and disseminated *Know Your Dose* acetaminophen safe use messages with their constituents and communities, including the American Association of Poison Control Centers, American Liver Foundation, National Fibromyalgia & Chronic Pain Association, National Headache Foundation, U.S. Pain Foundation and more.

The Coalition’s *Know Your Dose* campaign is one of many ongoing, coordinated educational initiatives that work in concert to drive appropriate acetaminophen use and prevent overdose. Aligned acetaminophen safe use education efforts also include:

Be MedWise and MUST for Seniors

Be MedWise and *Medication Use Safety Training (MUST) for Seniors* are public education initiatives promoting safe and appropriate medication use led by the National Council on Patient Information and Education (NCPPIE), a nonprofit coalition of consumer, healthcare professional, government, patient advocacy and public health organizations. Approximately one in four older adults takes at least five medicines daily.²⁶ Additionally, one in nine Americans over the age of 65 has Alzheimer’s disease or related dementia, potentially making daily medicine decisions difficult.²⁷ *MUST for Seniors* provides a ready-to-use PowerPoint presentation with presenter notes and handouts; tips for taking medications safely; and feature articles and videos with experts for use by older adults, caregivers and healthcare professionals for self-education and presentation of information in their



communities. A broad medicine safety campaign, *MUST for Seniors* includes the “Acetaminophen Safe Use for Seniors” guide with tips, “Questions to Ask Your Healthcare Professional About Acetaminophen” and more.

In addition, the *Be MedWise* campaign employs a wide variety of media channels—the mass media, print and broadcast advertising, Web, and consumer education materials—to help Americans select and use OTC medicines wisely. Grounded in consumer survey research and shaped by insights collected via multiple stakeholder forums, the initiative includes collaboration with the FDA and former U.S. Surgeon General Dr. Richard Carmona on a “Be MedWise Prescription for Taking OTC Medicines” pharmacy-based education campaign that reaches consumers when they are thinking about nonprescription medicines and making their purchasing decisions. The “Acetaminophen Safe Use College Resource Guide” and the “Acetaminophen Safe Use Program for Teen Influencers” offer customized content for teens, college students and older adults, including education modules on label reading in general and specific instructions on the safe use of acetaminophen.

Script Your Future and *Take With Care*

The National Consumers League (NCL) leads two medicine safety education campaigns: *Script Your Future* and *Take With Care*. *Script Your Future* is a public education program to raise awareness among consumers, family caregivers and healthcare professionals of the importance of medication adherence and taking medicines as directed. Poor medicine adherence—from delaying refills to not following the dosing instructions

Over the last three years, acetaminophen safe use messages from these efforts have been seen by consumers more than

1,000,000,000 times



on a medicine label—leads to morbidity, mortality and avoidable healthcare costs. *Script Your Future* brings together stakeholders in healthcare, business and government in six targeted cities. For healthcare providers, the campaign offers guidance on how to improve communication with patients. For patients, the campaign offers practical tools to improve medication adherence. NCL's Take With Care initiative launched multimedia, teen-focused education on the appropriate use of OTC pain relievers, addressing common teen misconceptions about these medicines. The campaign focuses on the importance of reading and following labels, taking the labeled dose, and consulting with parents and healthcare professionals—leveraging the opportunity to educate teens about proper OTC pain medication use while they are young and medicine use habits are forming.

Get Relief Responsibly®

Individual drug manufacturers are also conducting educational campaigns. For example, McNeil Consumer Healthcare, the maker of Tylenol®, launched the Get Relief Responsibly® education initiative in 2011 to increase knowledge of appropriate use of acetaminophen-containing medicines, change behavior, and, over time, reduce acetaminophen-related overdose and liver injury. The Get Relief Responsibly® campaign focuses on three key channels: 1) consumer education targeted to consumers most at risk, based on attitudinal and behavioral factors that research has shown to be associated with taking more than the maximum daily dose of acetaminophen, 2) retailer programs to target acetaminophen purchasers, and 3) professional education, as frequent users of acetaminophen also frequently interact with healthcare professionals.

Grounded in comprehensive consumer behavior research, Get Relief Responsibly® education initiative results indicate the program is having a positive impact. For example, consumers exposed to the campaign's digital media education efforts reported a 20 percentage point increase in acetaminophen issue awareness and a 14 percentage point increase in intent to change future behavior when taking acetaminophen (compared to control). In a recent survey, pharmacists who received Get Relief Responsibly® patient education materials reported they were more likely to counsel their patients about appropriate acetaminophen use (16 percentage points higher than control). Consumers and healthcare professionals can find useful online resources at GetReliefResponsibly.com, including a Medicine Checker tool to search medicines to see which ones contain acetaminophen. The site also includes educational videos, medicine safety tips, and guides on how to read medicine labels.²⁸

U.S. Food and Drug Administration

The FDA has promoted appropriate use of acetaminophen to consumers and healthcare professionals through a Use Acetaminophen Safely education campaign that includes consumer safety updates, educational videos and content within its Medicines in My Home campaign. Additionally, the agency's Safe Use Initiative focuses on reducing the preventable risk from acetaminophen overdose via public and private collaborations, including partnerships with the National Council for Prescription Drug Programs, the Acetaminophen Awareness Coalition and others.²⁹

Healthcare Professional Education

Numerous healthcare provider organizations have hosted continuing professional education focused on acetaminophen and made resources available to members. For example, the American Pharmacists Association developed a continuing pharmacy education program that prepares pharmacists to engage and communicate with patients on the safe and effective use of acetaminophen. The National Council for Prescription Drug Programs has published white papers, and educational resources for healthcare professionals have been made available by groups including the FDA, Alliance for Aging Research and its Silver Book series, and the Gerontological Society of America.

Product Changes to Promote Safe and Appropriate Use

Low ingredient awareness regarding the content of acetaminophen-containing medicines has been identified as a contributing factor to unintentional overdose.³⁰ Over the last five years, manufacturers and pharmacies have worked closely with the FDA, healthcare provider and pharmacist groups, and consumer health advocates to promote safe acetaminophen use by making changes to products, packaging and labeling. Consistency and visibility across OTC and prescription drug labels is a critical step to enable consumers and patients to identify and compare ingredients and take steps to improve the safe use of acetaminophen.³¹ Such changes have included:

- ▶ **Enhanced visibility of acetaminophen in OTC medicines via labeling changes:** All OTC medicines that contain acetaminophen now prominently display the word “acetaminophen” on the front panel of packaging to make it easier for consumers to identify this ingredient. OTC medicines with acetaminophen also highlight or bold “acetaminophen” on the “Drug Facts” label, and liver and concomitant use warnings are standardized across all products.

► **Limited levels of acetaminophen in prescription products:**

The amount of acetaminophen in prescription combination products is limited to 325 mg per unit dose.

► **Improving prescription labeling:** Most U.S. pharmacies have removed the “APAP” abbreviation, and the majority of prescription container labels for two-ingredient acetaminophen-opioid prescriptions contain the full spelling of acetaminophen, per the recommendations of the National Council for Prescription Drug Programs.³² As a result, the word “acetaminophen” is now more visible on labels of prescription medicines that contain acetaminophen and is accompanied by a standard concomitant use warning, such as: “This has acetaminophen. Don’t take with other medicines that have acetaminophen (prescription or nonprescription). Too much can cause liver damage.”

4. CONCLUSION

Working Together: Healthcare Professionals and Patients

As the healthcare landscape continues to evolve, more advances and innovations in medicines to meet the health needs of Americans will emerge. Ensuring patients and consumers use medicines safely will remain a top priority. This will require ongoing commitment and engagement from all sectors—healthcare professionals, drug manufacturers, government agencies, pharmacies and patients. There is a role for everyone to play to make sure patients and consumers use prescription and OTC medicines safely, read and follow the information on their medicine labels, and become familiar with the active ingredients in the medicines they take.

May cause drowsiness. Use care when operating a car or dangerous machines. Don't drink alcohol when taking this medicine.

This has acetaminophen. Don't take with other medicines that have acetaminophen (prescription or nonprescription). Too much can cause liver damage. Questions? Ask your doctor or pharmacist.

Taking more of this medicine than recommended may cause serious breathing problems.

Orig: 10/31/2011
Date filled: 10/31/2011
Discard after: 10/31/2012

This is a white, oval-shaped tablet with no imprint

CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PATIENT FOR WHOM IT WAS PRESCRIBED.



Local Pharmacy

1234 Winding Street
Fort Washington, PA 12345

John Smith

3254 Maple Street Fort Washington, PA, 12345

Brandname

hydrocodone/acetaminophen
X mg / XXX mg

Take 1 tablet by mouth every
4-6 hours as needed for pain

Qty: 30

Refills: 0

Pharmacy phone: (609) 555-5562

Rx # A123456

Prescriber: Dr. Johnson

Education is an effective tool to increase knowledge of medicine ingredients, risks and safe use practices, which are key factors in reducing unintentional acetaminophen overdose. Coordinated, comprehensive and robust educational initiatives engaging a broad range of aligned stakeholders have successfully been put in place in recent years to create a “surround sound” of educational messages promoting safe use across multiple channels and have demonstrated impact on consumer knowledge and attitudes.

The Acetaminophen Awareness Coalition points consumers to four simple steps for acetaminophen safe use:

1. Always read and follow the medicine label
2. Know if your medicines contain acetaminophen
3. Never take two acetaminophen-containing medicines at the same time
4. Ask your healthcare professional or pharmacist if you have questions

All consumers, regardless of what medicines they take to treat their health conditions, will be well-served by reminders and reinforcements that urge them to always read and follow the labels and product inserts that come with each medicine. For all sectors, adopting and sharing consistent and tested educational messages that are understandable, relevant and actionable is crucial. We encourage more pharmacies, more healthcare professionals and more health-involved stakeholder groups to work together to disseminate safe medicine use education and resources. The Coalition itself provides educational materials, including posters and brochures in English and Spanish, for display and distribution in waiting rooms, exam rooms and pharmacy counters. These are available free of charge and can be ordered via www.KnowYourDose.org/order.

When taken as directed, acetaminophen is safe and effective and an important and trusted pain reliever and fever reducer option for many. Used for decades by millions of people, it is one of the most widely used medicines in the United States. But when taken in overdose, it can cause liver damage and even death. Although very rare, particularly in the context of acetaminophen's widespread use, liver injury from acetaminophen remains a public health concern. We have solid insights into the behaviors associated with exceeding labeled doses of acetaminophen, as well as evidence that education increases safe use knowledge and awareness of risks. This is key, as increased knowledge of medicine ingredients and dosing instructions decreases the risk of acetaminophen overdose. With this understanding, we must continue our collaboration and education efforts about the importance of using acetaminophen appropriately. When education is readily accessible and patients and healthcare professionals are communicating openly and clearly about acetaminophen safety, it is expected that the effects on consumer awareness and knowledge will continue to be positive.



EDUCATIONAL RESOURCES

HOW TO READ YOUR MEDICINE LABEL

Knowing how to read the labels on prescription and over-the-counter medicines is an important step in making sure you use medicines appropriately. Always keep your medicine in the original packaging so that you have proper dosing information on hand.

PRESCRIPTION LABEL

Warnings

Warnings are specific to the medicine you are taking. Always read the warnings before taking your medicine.

Expiration Date

Medicines expire. You should not take a medicine after the expiration date.

Pharmacy Information

Your local pharmacy name, address and phone number and the name of the doctor who prescribed your medicine will be listed. Contact your pharmacist if you have any questions about your prescription.

Your prescription (Rx) number is unique to your medicine and helps the pharmacist ensure you go home with the correct prescription.

May cause drowsiness. Use care when operating a car or dangerous machines. Don't drink alcohol when taking this medicine.

This has acetaminophen. Don't take with other medicines that have acetaminophen (prescription or nonprescription). Too much can cause liver damage. Questions? Ask your doctor or pharmacist.

Taking more of this medicine than recommended may cause serious breathing problems.

Orig: 10/31/2011
Date filled: 10/31/2011
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Brandname

hydrocodone/acetaminophen
X mg / XXX mg

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4-6 hours as needed for pain

Qty: 30

Refills: Ø

Pharmacy phone: (609) 555-5562

Rx # A123456

Prescriber: Dr. Johnson

OVER-THE-COUNTER LABEL

Active Ingredient

This section indicates the ingredient or ingredients that make the medicine work. It is especially important to pay attention to this section if you are taking more than one medicine—whether OTC or prescription—to make sure you are not taking an excessive amount of the same active ingredient. Too much of an active ingredient can be harmful.

Uses

This section explains the symptoms or illnesses for which the product should be used. Only use products that treat the symptom(s) you have. If you need help choosing a product, ask your pharmacist or other healthcare professional.

Warnings

There are times you should not take a medicine. The warnings section explains these situations, and also tells you possible side effects, when a doctor or other healthcare professional needs to be consulted, and when to stop taking a product. If you have questions, ask a pharmacist or other healthcare provider.

Directions

This section tells you exactly how and when to take a medicine. Remember that these directions are not suggestions or recommendations. They should be followed exactly, except under a doctor's specific advice. Taking a higher dose of a medicine more often or for a longer period of time than the medicine label says can be dangerous.

Other Information

This section tells you other important information about your medicine, such as where to store it and at what temperature ranges. Most medicines should be kept away from heat and humidity to help them stay effective longer. Always keep medicines out of the reach and sight of children.

Inactive Ingredients

The inactive ingredients section includes important information about what is in your medicine in addition to the active drug ingredients. It is especially important if you or a loved one has a known allergy.

Questions?

Always talk to your healthcare professional if you have any questions. You can also call the toll-free number listed in this section.

Purpose

This section tells you what treatment type—or category—of medicine the product is in, such as a pain reliever or fever reducer.

Drug Facts

Active ingredient (in each caplet)

Acetaminophen XXX mgPain relieve/fever reducer

Purpose

Uses

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

Warnings

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

- take more than X caplets in 24 hours, which is the maximum daily amount
- take with other drugs containing acetaminophen
- drink 3 or more alcoholic drinks every day while using this product

Do not use:

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen ask a doctor or pharmacist
- if you are allergic to acetaminophen or any of the inactive ingredients in the product

Ask a doctor before use if you have: liver disease

Ask a doctor or pharmacist before use if you are: taking the blood thinning drug warfarin

Stop use and ask a doctor if:

- pain gets worse or lasts more than 10 days
 - fever gets worse or lasts more than 3 days
 - new symptoms occur
 - redness or swelling is present
- These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Directions

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

adults and children
12 years and over

- take X caplets every X to X hours while symptoms last
- do not take more than X 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 adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- store between 20-25° C (68-77° F)
- do not use if carton is opened or neck wrap or foil inner seal imprinted with "Safety Seal®" is broken or missing**
- see end panel for a lot number and expiration date

Inactive Ingredients

carnauba wax*, castor oil*, corn starch, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, polyethylene glycol*, powdered cellulose, pregelatinized starch, proylene glycol, shellac, sodium starch glycolate, titanium dioxide *contains one or more of these ingredients

Questions or comments?

call 1-877-XXX-XXXX

KNOW YOUR DOSE CAMPAIGN POSTERS



Acetaminophen is in more medicines than you might think

It's the most common drug ingredient in America, found in more than 600 different prescription and over-the-counter medicines, including pain relievers, fever reducers, and sleep aids as well as cough, cold, and allergy medicines. On prescription labels, acetaminophen is sometimes listed as "APAP," "acetam," or other shortened versions of the word. When used as directed, acetaminophen is safe and effective, but there is a limit to how much you can take in one day. Taking more than directed is an overdose and can lead to liver damage. So know your dose – always read and follow the label and never take two medicines that contain acetaminophen at the same time.

For more information, talk to your healthcare professional or visit [KnowYourDose.org](https://www.KnowYourDose.org)
Acetaminophen Awareness Coalition



El acetaminofén está en más medicinas de lo que usted cree

El acetaminofén (también llamado paracetamol) se encuentra en más de 600 medicinas diferentes, incluyendo las medicinas de venta libre y con receta para la fiebre, la tos, la gripe, las alergias y el insomnio, además de las medicinas para el dolor (analgésicos). Si se siguen las instrucciones de uso, el acetaminofén es seguro y eficaz. Pero hay un límite a la cantidad que se puede tomar en un día. Si se toma más acetaminofén de lo indicado, se produce una sobredosis que puede causar daño al hígado.

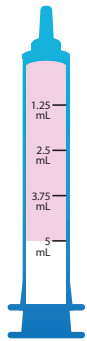
Siga estos tres pasos simples para usar acetaminofén de manera segura:

- ▶ Siempre lea la etiqueta de la medicina y siga las instrucciones.
- ▶ Averigüe si sus medicinas contienen acetaminofén.
- ▶ Nunca tome al mismo tiempo dos medicinas que contengan acetaminofén.

Para más información, hable con su proveedor de servicios de salud, visite KnowYourDose.org, o llame a Su Familia, la línea de ayuda en español al 1-866-783-2645

ACETAMINOPHEN FOR INFANTS AND CHILDREN

It is important to always read and follow the label when giving medicine to your child. This guide will help you give your child the right amount of acetaminophen. If possible, use weight to dose your child; otherwise, use age.



Always use the measured dosing device

(oral syringe or plastic cup) that comes with the product
(concentration 160 mg/5 mL)



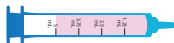










Use formulations made for infants and children, not adult products



Dose by weight (preferred) or age, according to the instructions on the medicine label or from your child's healthcare provider



Keep all medicine up and away and out of sight to avoid accidental ingestion by curious children

CHILD'S WEIGHT AND AGE	INFANTS' ACETAMINOPHEN SUSPENSION LIQUID 160 MG/5 ML	CHILDREN'S ACETAMINOPHEN SUSPENSION LIQUID 160 MG/5 ML	CHILDREN'S ACETAMINOPHEN TABLETS 80 MG
UNDER 2 YEARS If your child is under 2 years of age, be sure to ask your healthcare provider for the right dose.			
24-35 LBS 2-3 YEARS	 5mL (1 tsp)	 5mL (1 tsp)	 2 tablets
36-47 LBS 4-5 YEARS	—	 7.5mL (1 1/2 tsp)	 3 tablets
48-59 LBS 6-8 YEARS	—	 10mL (2 tsp)	 4 tablets
60-71 LBS 9-10 YEARS	—	 12.5mL (2 1/2 tsp)	 5 tablets
72-95 LBS 11 YEARS	—	 15mL (3 tsp)	 6 tablets

It is also important to check the amount (concentration) of acetaminophen in medicines for infants. In 2011, manufacturers changed liquid acetaminophen products for infants. Before this change, liquid acetaminophen products for infants were a different concentration than liquid acetaminophen for older children. Now, both infants' and children's acetaminophen are the same strength to standardize concentration and dosing across all single-ingredient liquid acetaminophen products. You can find the concentration for the medicine on the front of the medicine bottle. The new concentration is 160mg/5mL. Ask your healthcare provider if you have any questions.

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The Acetaminophen Awareness Coalition is a diverse group of organizations representing healthcare professionals and consumers whose members are committed to ensuring that acetaminophen is used only as labeled or directed. Coalition members include the Alliance for Aging Research, American Academy of Physician Assistants, American Association of Nurse Practitioners, American Pharmacists Association, CHPA Educational Foundation, National Association of Boards of Pharmacy, National Association of Chain Drug Stores Foundation, National Community Pharmacists Association, National Consumers League, and the National Council on Patient Information and Education.

The Coalition's *Know Your Dose* campaign is advised by the FDA's Safe Use Initiative, the Center for Disease Control and Prevention, and the American Academy of Pediatrics.

