

FROM POLICY^{TO} PRACTICE

AN INTERDISCIPLINARY LOOK AT LABELING CHANGES TO OTC ANALGESICS AND THE IMPLICATIONS FOR PATIENT CARE

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LEARNING OBJECTIVES

After reading this publication, the health care provider will be able to:

- Describe the role of over-the-counter (OTC) pain medications in a comprehensive approach for the assessment and treatment of persistent pain in older adults.
- Differentiate among OTC analgesics with regard to their safety profiles for use in older adults.
- Inform older adults and caregivers of labeling changes for acetaminophen and non-aspirin nonsteroidal anti-inflammatory drugs, with an emphasis on new warnings.
- Educate older adults and caregivers about appropriate use of OTC analgesics for older patients.

Introduction

The population of older adults in the United States—and around the world—is increasing dramatically. According to data in the U.S. Census Bureau report, *An Aging World: 2015*, the U.S. population aged 65 years and older will nearly double over the next 30 years, from 48 million to almost 88 million. The group of the “oldest old”—those aged 80 years and older—is expected to more than triple between 2015 and 2050.¹

The use of over-the-counter (OTC) medications, and OTC analgesics in particular, poses challenges in older adult populations. According to the Consumer Healthcare Products Association, 93% of adults in the United States prefer to treat their minor ailments with OTC medicines before seeking care from a health care provider.² Furthermore, adults 65 years of age and older use more prescription and OTC medications than any other demographic group, and they account for 30% of OTC medication use in the United States.^{3,4} Older adults are significantly more likely to experience an adverse drug reaction than younger adults, with a reported 61.5% of emergency department visits occurring among older adults because of adverse drug reactions.^{3,5,6}

Increased risk of adverse drug events in older adults results from age-related physiological changes, polypharmacy, drug interactions, and inappropriate prescribing and monitoring of drug therapy. Individuals over 65 years of age are also more likely to have chronic conditions that increase the risks of drug-disease interactions.⁷ Use of prescription drugs increases substantially with age, which further amplifies the risk of drug interactions and adverse effects.^{7,8} Among adults 60 years of age and older, more than 76% use two or more prescription drugs, and 37% use five or more.⁸

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Older individuals may not report pain because they think it is a normal part of aging or because they do not want to incur additional testing or medication; thus, careful assessment approaches are integral to patient care.^{12,13} Although pain is associated with many conditions that are common in older adults, pain should not be viewed as “normal.” It is important for clinicians and others who care for older adults to remember pain is a signal that something is wrong and needs to be addressed. Reports of pain should not be dismissed simply because the patient is older. Although the cause of the pain cannot always be cured, appropriate pain management is essential to preserve function and quality of life, regardless of the patient’s age.

When older adults use OTC analgesics, appropriate medication selection and safe use are paramount. Here, we review the management of pain in older adults, examine the appropriate use of OTC analgesics in the treatment of pain, explore safety considerations for the use of these medications by older adults, and describe recent labeling changes. Strategies for communicating safe use information to patients are also presented.

Pain in Older Adults

Pain may be either acute (a sudden reaction to noxious stimuli) or persistent (continuing for a prolonged period).^{9,10} Persistent pain is common in older adults, affecting more than half of those who live in the community and an even greater proportion of institutionalized older adults.¹¹ Persistent pain may arise from numerous conditions such as arthritis, cancer, neuralgias, vascular disease, trauma (e.g., osteoporotic fractures), and a myriad of other causes.¹⁰

Aging does not appear to decrease sensitivity to pain and, in fact, older adults may be more vulnerable to persistent pain due to a reduced capacity for pain modulation.¹¹ They may self-treat their pain, withdraw from routines, and/or develop substance-abuse disorders.¹¹

Persistent pain has a detrimental effect on function and quality of life. It can impact physical, mental, and social function as well as sleep and other measures of quality of life. Severe persistent pain can lead to a vicious cycle, in which patients do not engage in physical activity in an effort to avoid pain. This can lead to deconditioning and worsening psychological outlook, which then contribute to worsening pain and disability. In older adults, common adverse outcomes associated with persistent pain include functional impairment, falls, slow rehabilitation, mood changes, decreased socialization, and disturbed sleep and appetite.¹⁰

Assessing Pain

The first step in managing pain is to perform a comprehensive assessment, including diagnosis of any underlying conditions and identification of conditions (e.g., cardiovascular disease, renal failure, hepatic failure) that can influence the risks of various treatment options.^{10,14} Patient self-report scales may be used for appropriate patients and behavioral observation scales may be appropriate for patients with communication barriers (e.g., cognitive barriers).¹⁴ Additionally, assessment tools that evaluate the impact of pain on other functional domains (e.g., mobility, psychological well-being) may be used.

Management of Persistent Pain

Managing persistent pain is complex and multifactorial in any population. Disease-modifying interventions that can address the source of pain should be explored when possible. For patients whose cause of pain is

not curable, a comprehensive and interdisciplinary approach is required, including referrals to specialists (e.g., psychologists, physical therapists, occupational therapists) when appropriate. In addition to performing a comprehensive assessment, the patient care team should establish realistic patient-centered goals and implement evidence-based interventions that are individualized based on the patient's needs and preferences.¹¹

Although appropriate treatment of pain can reduce suffering and lead to improved functional outcomes, the benefits of any treatment must be weighed against the risks. Older patients are a heterogeneous population and therefore treatments must be individualized based on patient needs. Many patients benefit from a multimodal plan for pain management that includes both pharmacologic and nonpharmacologic approaches. Nonpharmacologic approaches include physical activity, cognitive behavioral therapy, and complementary and alternative medicine (e.g., massage, acupuncture). Dosages of pain medications for most patients should be started low and slowly titrated upward. Product labels for OTC analgesics state that they should only be used short term. Patients who have persistent pain should be evaluated by a health care provider, who may recommend ongoing use of an OTC analgesic as a component of a persistent pain management plan.

Nonpharmacologic Approaches

Multiple nonpharmacologic therapies can be used to treat persistent pain in older adults. Physical activity is widely recommended for many types of pain and patient levels of function. However, pain itself may act as a barrier to physical activity and can create a vicious cycle of inactivity,

leading to worsening pain and the potential for reduced mobility and deconditioning, which can result in increased susceptibility to falls, social isolation, and negative psychological sequelae. Beyond physical activity, other physical interventions include transcutaneous electrical nerve stimulation, use of assistive devices, massage, manipulation, and heat and ice treatment.¹⁵

Depression and anxiety are common in patients with persistent pain and can worsen the patient's experience of pain. Breaking this vicious cycle is important for improving the management of many persistent painful conditions, such as osteoarthritis and low back pain. Psychosocial approaches to persistent

pain include patient education, training in self-management skills and coping skills, cognitive behavioral therapy, and social support.

Pharmacologic Therapy: Focus on OTC Analgesics

When pharmacologic therapy is used to help manage persistent pain, medications must be carefully selected to minimize their risks, particularly among older adults. Physiologic changes that occur with aging can affect the pharmacokinetics and pharmacodynamics of medications, increasing the risk for adverse events.¹⁰ Age-related physiologic changes that impact pain and pharmacokinetics of analgesics are shown in Table 1.

TABLE 1. EFFECT OF AGE-RELATED PHYSIOLOGIC CHANGES ON PAIN AND PHARMACOKINETICS

Physiologic Process	Change With Advancing Age
Peripheral pain fibers	Structural, functional, and biochemical changes of peripheral nerves may raise pain threshold
Pain modulation system	Favors sensitization of pain with diminished pain inhibitory system activity
Pain perceptual system	Altered structure and functioning of key pain processing centers of the brain
Immune system	Alterations in peripheral mast cells and central microglia contribute to neuroinflammation
Gastrointestinal system	Slowed motility, blood flow, or active transport mechanisms may affect drug uptake
Drug distribution	Decreased body water may reduce distribution of water-soluble drugs Increased body fat can cause accumulation and longer half-lives of fat-soluble drugs Decreased serum albumin alters protein binding and increases risk for drug interactions
Drug metabolism	Reduced hepatic size and blood flow may reduce first-pass metabolism of some drugs
Drug elimination	Decreased renal structure, function, and blood flow reduces excretion of drugs and metabolites
Pharmacodynamic changes	Decreased receptor density Increased sensitivity to therapeutic effects and adverse events

Source: Reference 11.

Commonly used OTC analgesics include acetaminophen and the non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) ibuprofen and naproxen. Acetaminophen and NSAIDs may also be found as a component of both nonprescription and prescription products in combination with other medications (e.g., OTC cough and cold products, prescription analgesics). Several NSAIDs are available by prescription, including higher-dosage versions of ibuprofen and naproxen, diclofenac, and selective cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib). Many of the considerations affecting the selection of OTC analgesics focus on the adverse events associated with these products.

Acetaminophen

Acetaminophen is one of the most widely used analgesics in the United States and has a well-established record of safety and efficacy when used according to labeled directions.¹⁶ Thus, it is often recommended as an initial and ongoing treatment for mild-to-moderate pain in older adults.¹⁰ Acetaminophen can lead to severe liver damage if more than 4,000 mg of acetaminophen is taken in a 24-hour period, if an acetaminophen-only product is taken with other drugs containing acetaminophen, or if 3 or more alcoholic drinks are consumed on days when using an

acetaminophen product. Liver injury from acetaminophen overdose is relatively rare given acetaminophen's widespread use. Nevertheless, it remains an important public health issue despite ongoing regulatory and educational efforts over the past several years to support safe use. Patients are advised not to exceed the labeled dosage and to consider their acetaminophen intake from all products. Patients with liver disease are also advised to ask a health care provider before using acetaminophen.¹⁰ Because acetaminophen is available in many different medications, including OTC analgesics, cough and cold products, sleep aids, and prescription analgesics, patients may inadvertently exceed the maximum daily dosage.

NSAIDs

NSAIDs are a widely used class of drugs for the treatment of mild-to-moderate pain. Although nonprescription NSAIDs may be reasonably safe for some patients when used according to labeling instructions, risks increase dramatically when OTC doses are exceeded or when they are used for longer than directed. Older adults are at higher risk for adverse events from NSAIDs, including the COX-2 inhibitors. In one study of adults 65 years of age and older, NSAIDs were implicated in 23.5% of cases of adverse drug

reactions resulting in hospitalizations.¹⁷ Gastrointestinal (GI) bleeding and cardiovascular events are the most common adverse events associated with older adults taking nonselective NSAIDs and COX-2 inhibitors, respectively. Renal adverse effects can also occur with NSAIDs, irrespective of COX-2 selectivity.

Gastrointestinal Adverse Events

Dyspepsia is a less severe adverse event that commonly occurs in patients using NSAIDs. GI bleeding is a more serious outcome of NSAID use and results in approximately 103,000 hospitalizations, 16,500 deaths, and over \$2 billion in direct health care costs annually.¹⁸ GI bleeding may occur within the first week of therapy, and the risk of GI bleeding or death increases with age (Table 2).^{19,20} Risks are increased when OTC non-aspirin NSAIDs are combined with prescription non-aspirin NSAIDs or other OTC NSAIDs such as low-dose aspirin (which many older adults use daily for cardioprotection) and alcohol.^{21,22} These events can occur at any time during use and without warning symptoms. Those aged 60 years and older are at greater risk for serious GI events.

Cardiovascular Adverse Events

Non-aspirin NSAIDs are associated with an increased risk of serious cardiovascular events, including myocardial infarction, stroke, and congestive heart failure episodes, all of which can be fatal.^{23,24} There is a substantial body of data that supports this conclusion, although the specific degree of increased risk is not firmly established. Higher dosages appear to be associated with higher risk. This risk may occur as early as the first weeks of treatment and increase with duration of use.¹⁶

TABLE 2. RISKS OF GASTROINTESTINAL BLEEDING AMONG PATIENTS USING NONSTEROIDAL ANTI-INFLAMMATORY DRUGS		
Age Group	Serious Bleed (per 10,000 patients)	Death From a Bleed (per 10,000 patients)
75 years or older	91	15
65 to 74 years	17	3
Younger (16 to 44 years)	5	1

Source: Reference 20.

Individual patient risk factors—such as comorbidities, concomitant medications and drug interactions, doses used, and duration of treatment—need to be taken into consideration when making treatment recommendations.

The relative increase of serious cardiovascular events over baseline associated with NSAID use appears to be similar in those with and without known cardiovascular disease or risk factors for cardiovascular disease. However, patients with known cardiovascular disease or risk factors have a higher absolute incidence of serious cardiovascular events due to their increased baseline rate.¹⁶

Notably, some non-aspirin NSAIDs, such as ibuprofen, can interfere with the antiplatelet effect of low-dose aspirin used for cardioprotection by blocking aspirin's irreversible COX-1 inhibition.¹⁶

Renal Effects

NSAIDs can negatively affect renal function in older patients. Renal failure is more common in patients who are older than 65 years of age; those with hypertension, heart failure, or renal disease; and those using diuretics, angiotensin-converting enzyme inhibitors, or angiotensin receptor blocking agents.²⁵

Opioids and Adjunctive Therapies

Opioids may be appropriate for carefully selected and monitored patients. The risks associated with NSAIDs in older adults may justify the use of opioids, particularly for individuals at heightened risk for NSAID-associated side effects. When opioids are prescribed for older adults with moderate-to-severe pain, careful ongoing monitoring is required to ensure that the benefits of opioid therapy continue to outweigh the risks.¹⁰

Adjunctive therapies may be appropriate for patients with specific painful conditions. For example,

TABLE 3. AMERICAN GERIATRICS SOCIETY GUIDELINE CAUTIONS REGARDING OVER-THE-COUNTER ANALGESICS	
Acetaminophen	NSAIDs
■ Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours, with other drugs containing acetaminophen, or 3 or more alcoholic drinks every day while using this product. ■ Warnings and cautions include hepatic insufficiency, chronic alcohol abuse, or dependence. ■ Maximum daily recommended dosage of 4,000 mg per 24 hours should not be exceeded, including from both single-ingredient and combination products.	■ Older persons taking nonselective NSAIDs should consider using a PPI or misoprostol for GI protection. ■ Patients taking a COX-2 selective inhibitor with aspirin should use a PPI or misoprostol for GI protection. ■ Patients should not take more than one nonselective NSAID or COX-2 selective inhibitor at a time. ■ Patients taking low-dose aspirin as a cardioprotective agent should not use ibuprofen. ■ All patients taking nonselective NSAIDs and COX-2 selective inhibitors should be routinely assessed for GI and renal toxicity, hypertension, heart failure, and other drug-drug and drug-disease interactions.

COX-2 = cyclooxygenase-2; GI = gastrointestinal; NSAID = nonsteroidal anti-inflammatory drug; PPI = proton pump inhibitor.

Source: Reference 10.

several anticonvulsant agents are considered first-line treatment for individuals with neuropathic pain.

Guideline Recommendations for the Use of OTC Analgesics

NSAIDs may be used with extreme caution in highly selected older adults, including those who have failed therapies that may have been more appropriate or whose therapeutic goals have not been met.¹⁰ OTC NSAIDs' label warnings advise patients to ask their doctors before use if they have a history of stomach problems such as bleeding, high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had or are at risk of having a heart attack or stroke.

Several guidelines address the management of pain in older adults, including those from the American Geriatrics Society (AGS). Although

the AGS Guideline for Persistent Pain in Older Persons was published in 2009, the recommendations are still relevant. Recommendations from AGS regarding the use of acetaminophen include:¹⁰

- Acetaminophen should be considered as initial and ongoing pharmacotherapy in the treatment of persistent pain, particularly musculoskeletal pain, owing to its demonstrated effectiveness and good safety profile (high quality of evidence; strong recommendation).
- Nonselective NSAIDs and COX-2 selective inhibitors may be considered rarely, and with extreme caution, in highly selected individuals (high quality of evidence; strong recommendation).

The AGS guideline also offers several cautions regarding the use of NSAIDs (Table 3). In older persons,

GI-related toxicity from NSAID use increases in frequency and severity with age. Coadministration of gastroprotective agents such as proton pump inhibitors is often recommended to address this potential occurrence.¹⁰

A more recent guideline on pain in older adults was published in 2013 by the British Geriatrics Society—and endorsed by the British Pain Society—with recommendations that concur with the AGS guideline. These include advice that acetaminophen should be first-line therapy for both acute and persistent pain, particularly musculoskeletal pain, and NSAIDs should be used with caution in older people only after other safer treatments (e.g., acetaminophen, nonpharmacologic approaches) have not provided sufficient pain relief.²⁶

Beers Criteria

Various strategies have been developed to address the heightened risks of several medications in older adults. The Beers Criteria for Potentially Inappropriate Medication Use in Older Adults, published by AGS, lists medications that are best avoided by older adults in general, medications that should be avoided in older adults with certain disease

states, and medications that require reduced dosages or heightened monitoring. The most recent version of the Beers criteria, released in 2015, also identifies medications that require dose adjustment based on kidney function and drug-drug interactions.²⁷

According to the Beers criteria, use of nonselective NSAIDs are considered potentially inappropriate in older adults because of the increased risk of GI bleeding or peptic ulcer disease in high-risk groups, including those aged 75 years or older or taking oral or parenteral corticosteroids, anticoagulants, or antiplatelet agents. Use of a proton pump inhibitor or misoprostol reduces but does not eliminate this risk. Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occur in approximately 1% of patients treated for 3 to 6 months and in approximately 2% to 4% of patients treated for 1 year; these trends continue with longer duration of use.²⁷ The criteria specify that older adults should avoid chronic use, unless alternatives are not effective, and patients should use gastroprotective agents (i.e., proton pump inhibitors or misoprostol).²⁷

The Beers criteria further specify that NSAIDs should be avoided in patients who have:²⁷

- Heart failure (because of the potential to promote fluid retention and exacerbate heart failure).
- History of gastric or duodenal ulcers (which may exacerbate existing ulcers or cause new or additional ulcers).
- Chronic kidney disease stages 4 or 5 (creatinine clearance <30 mL/min).

FDA Safe Use Initiative

The U.S. Food and Drug Administration (FDA) launched its Safe Use Initiative as a public-private partnership across the health care community as a way to identify and prevent specific medication-related adverse events. The Safe Use Initiative has addressed several issues relating to the use of acetaminophen and NSAIDs (as well as other pain management topics related to opioid use that are beyond the scope of this discussion).¹⁶

Acetaminophen Changes

A key factor that influences therapeutic duplication (e.g., taking multiple products that contain acetaminophen such as multi-symptom cough and cold products and analgesics) is that patients may be unaware that multiple medications contain acetaminophen, particularly if they do not carefully review package labels. Furthermore, although active ingredients are listed on OTC labels, prescription labeling may not be as clear; for instance, the abbreviation APAP may be used on a prescription label and not be recognized as acetaminophen by older adults or caregivers (e.g., family members, home health aides).



The Safe Use Initiative and a broad group of stakeholders, including the National Council for Prescription Drug Programs (NCPDP), formed the Acetaminophen Best Practices Task Group. In 2013, this task group released version 1.1 of a white paper titled “NCPDP Recommendations for Improved Prescription Container Labels for Medicines Containing Acetaminophen.” The white paper provided recommendations intended to harmonize labeling across OTC and prescription products containing acetaminophen in order to make it easier for consumers to: (1) identify when their prescription pain reliever contains acetaminophen; (2) compare active ingredients on their prescription and OTC labels; and (3) take action to avoid using multiple medicines that contain acetaminophen. Recommendations included the following:¹⁶

- Complete spelling of acetaminophen and all other active ingredients on the pharmacy labels of acetaminophen-containing prescription medicine, eliminating the use of abbreviations, acronyms, or other shortened versions for active ingredients.
- A standardized concomitant use and liver warning label for these medicines applied on the pharmacy container.
- Formatting and wording on pharmacy container labels consistent with plain language and health literacy principles.
- A stakeholder call to action: adopt, implement, adhere, communicate, and educate.

FDA has an ongoing public education campaign about the safe use of acetaminophen—the Acetaminophen Awareness Coalition’s “Know Your Dose” campaign (see resources box on page 10).

Additionally, in 2014, FDA lowered the maximum amount of acetaminophen allowed per dosage unit of combination prescription analgesics from 500 mg/dosage unit to 325 mg/dosage unit.

NSAID Labeling Changes

The risk of heart attack and stroke with non-aspirin NSAIDs was first added as a boxed warning to prescription NSAID labels in 2005. More recently, FDA requested that the warnings be further strengthened on prescription labeling in 2015 and on OTC non-aspirin NSAID labels in 2016.²⁴

The label warning of the cardiovascular risk of non-aspirin NSAIDs will be implemented on all OTC packages. The major updates to the Warning sections of Drug Facts labeling state the following:²⁴

- Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Ask a doctor before use if:

- You have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or have had a stroke.

Stop use and ask a doctor if:

- You have symptoms of heart problems or stroke:
 - Chest pain
 - Trouble breathing
 - Weakness in one part or side of body
 - Slurred speech
 - Leg swelling

FDA launched its Safe Use Initiative as a public-private partnership across the health care community as a way to identify and prevent specific medication-related adverse events.

TABLE 4. IMPORTANT PRECAUTIONS FOR PATIENTS TAKING OVER-THE-COUNTER ANALGESICS**Patients should be instructed to:**

- Take your medication exactly as your health care provider instructed.
- Ask about possible side effects and promptly report any that you experience.
- Tell your health care provider and pharmacist about any bad reactions you have had to medications in the past.
- Read and follow the Drug Facts label each time you use an over-the-counter medicine for pain relief.
- Take **only** 1 medicine that contains the same type of active ingredient at a time.
- Discard medications that are expired.
- Limit the amount of alcohol that you consume to fewer than 3 drinks per day.

Source: References 30 and 31.

TABLE 5. SYMPTOMS THAT SHOULD PROMPT PATIENTS USING OVER-THE-COUNTER ANALGESICS TO CONTACT A HEALTH CARE PROVIDER, ACCORDING TO PRODUCT LABELS

Symptom	Aspirin	Ibuprofen	Naproxen Sodium	Acetaminophen
Signs of stomach bleeding:				
■ Feel faint	X	X	X	
■ Vomit blood	X	X	X	
■ Have bloody or black stools	X	X	X	
■ Stomach pain that does not get better	X	X	X	
Pain gets worse or lasts more than 10 days	X	X	X	X
Fever gets worse or lasts more than 3 days	X	X	X	X
Redness or swelling in the painful area	X	X	X	X
Any new symptoms appear	X	X	X	X
Difficulty swallowing			X	
Feels like the pill is stuck in throat			X	
Hearing problems or ringing in ears	X			

Educating Patients About OTC Analgesic Use

Because OTC medications are so widely used, there is a general sense that they are harmless and safe for everyone. Their availability in supermarkets and convenience stores, where they can be purchased without an opportunity for professional advice on their use or potential side effects, reinforces this common misperception.²⁸ Health care providers have a responsibility

to inform patients and caregivers that this is not the case.²⁹ Patients should be educated to always carefully read and follow the Drug Facts label found on all OTC products and to follow the directions. Important precautions for the use of OTC analgesics are listed in Table 4.^{30,31}

However, there is often a communication gap between patients and their health care providers when it comes to discussing medications. The National Council on Patient Information

and Education (NCPIE) conducted a survey to examine patients' knowledge, attitudes, and behaviors regarding medication risk and safety information. Key findings of this survey include:³²

- Approximately 62% of respondents were unaware of any safety warnings about their medications.
- Of those who reported that they were aware of a safety warning, 75% could not recall what the warning was or which medication it was for.

TABLE 6. DOSING RECOMMENDATIONS FOR OVER-THE-COUNTER ANALGESICS

Medication	Strength and Dosage Form	Directions	Maximum Daily Dosage
Aspirin	325-mg tablets	1 or 2 tablets every 4 hours, or 3 tablets every 6 hours.	Not to exceed 12 tablets in 24 hours (3,900 mg).
Acetaminophen	325-mg tablets	2 tablets every 4 to 6 hours while symptoms last.	Do not exceed 10 tablets in 24 hours (3,250 mg), unless directed by a doctor.
	500-mg tablets	2 tablets every 6 hours while symptoms last.	Do not take more than 6 tablets (3,000 mg) in 24 hours, unless directed by a doctor.
Ibuprofen	200-mg caplets	1 caplet every 4 to 6 hours. If pain or fever does not respond, take 2 caplets.	Do not exceed 6 caplets (1,200 mg) in 24 hours.
Naproxen Sodium	220-mg tablets	1 tablet every 8 to 12 hours while symptoms last. Take 2 tablets initially within the first hour.	Do not exceed 2 tablets in 12 hours, or 3 tablets in 24 hours (660 mg).

- Most respondents indicated that they prefer both written and verbal communication about drug safety when visiting their provider or getting a prescription filled.

If the completed patient assessment indicates medication use as part of the treatment plan, it is vitally important that clinicians cover the following points with their patients:

- What the drug is for, how to take it, and the reason the specific medication is recommended for them.
- What to expect (in terms of relief and possible adverse events) and what side effects should prompt a call to a health care professional (Table 5).
- Read OTC product labels every time for the most current information about how to use the product safely.

Patients should also be advised to keep a list of all their medications

and share it with all their health care professionals.³³ This action can help prevent therapeutic duplication as well as drug-drug interactions.

OTC Analgesic Dosing

The general rule for patients regarding dosing of OTC medications is to take the smallest effective dose for the shortest possible duration.³⁴ The Drug Facts label for OTC analgesics lists dosing information for the product (Table 6). Older adults must be educated that increasing the dosage of their medication beyond the recommended dosage range increases the risk of adverse events.

Summary

Pain management in older adults is challenging and frequently managed with acetaminophen and NSAIDs. In recent years, there have been several changes to the labeling of these products; this publication discusses those updates and

focuses on the latest labeling changes—implementation of 2015 FDA warnings about increased cardiovascular risk with non-aspirin NSAIDs. Health care providers are strongly encouraged to ensure that this information is clearly communicated to patients.

Aging, comorbid conditions, chronic health disorders, and pain medication history are among the many issues that affect the safety of OTC medications in older adults. Emphasis is on those medications that should be avoided by older patients. It is essential that health care providers work with older adults to manage their pain to improve function and quality of life. When pain management interventions include medications, providers should educate older patients, as well as caregivers, when appropriate, about safe drug use, side effects, and dosing recommendations.

ONLINE RESOURCES REGARDING SAFE USE OF OVER-THE-COUNTER ANALGESICS

Source	Resource	Website
Acetaminophen Awareness Coalition	Know Your Dose	www.knowyourdose.org
Consumer Healthcare Products Association	Know Your OTCs	www.knowyourotcs.org
Johnson & Johnson Consumer Inc.	GET RELIEF RESPONSIBLY®	www.getreliefresponsibly.com
National Council for Prescription Drug Programs	NCPDP Recommendations for Improved Prescription Container Labels for Medicines Containing Acetaminophen—version 1.1	www.ncdp.org/NCPDP/media/pdf/wp/NCPDPacetaminophenWPv1.1_31jan2013.pdf
National Council on Patient Information and Education	Acetaminophen Safe Use for Seniors Toolkit	www.bemedwise.org/acetaminophen/seniors
	Be MedWise	www.bemedwise.org
U.S. Food and Drug Administration	Acetaminophen Information	www.fda.gov/acetaminophen
	Safe Use Initiative—Acetaminophen Toxicity	www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/ucm188762.htm
	Using Acetaminophen and Nonsteroidal Anti-inflammatory Drugs Safely	www.fda.gov/otcpaininfo
	Medicines in My Home	www.fda.gov/medsinmyhome

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