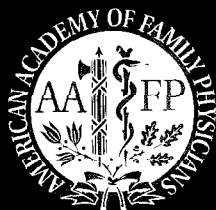


Appropriate Use of Common OTC Analgesics and Cough and Cold Medications

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Appropriate Use of Common OTC Analgesics and Cough and Cold Medications

An American Family Physician Monograph

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Introduction

Market survey data suggest that more than 70 percent of American adults and about 50 percent of American children take nonprescription, over-the-counter (OTC) medications in any given month.^{1,2} Is this treatment beneficial? Is it cost-effective? Are the risks of adverse effects acceptably low? The answers to all of these questions can be “yes” if the patients are guided by reliable information but can be “no” if the wrong product or the wrong dose is taken by the wrong patient.

Should physicians know what OTC products their patients are taking? Should they try to guide the self-treatment process? The evidence suggests that the answer to these two questions is “yes.” The ready availability of OTC products provides both challenges and opportunities to medical professionals. The challenge is to educate patients to use OTC products properly. The benefit to patients is prompt, cost-effective relief of symptoms. The benefit to physicians is a reduction in office visits and telephone calls related to minor, self-limited condi-

tions, freeing them to focus their attention on more productive aspects of health care.

OTC products are “real” medications that can offer substantial benefits to patients. They can cause significant side effects, but the fact that they are available without prescription under U.S. Food and Drug Administration (FDA) regulations indicates that the risk of untoward effects is acceptably small.

This resource guide gives family physicians a basic overview of the most commonly used OTC medications: analgesics, decongestants, antihistamines, antitussives and expectorants. It covers their mechanisms of action, side effects, potential for drug-drug interactions and use in special patient populations. The guide also gives specific tips and tools for facilitating the conversation with patients about their use of these medications, as well as materials designed to educate patients about the topic and help them understand how to choose and safely use these medications.

OTC Medications

According to standards established by the FDA, the following criteria must be met before a medication can be marketed without a prescription:

- The medication must possess a low risk of side effects at therapeutic doses;
- patients must be able to self-diagnose their symptoms and select an appropriate treatment; and
- the product must be labeled in such a manner that the average consumer can read and understand the indications, contraindications and directions for use of the product.³

Aside from the thousands of drugs that are originally classified as OTC, many medications that were originally classified as prescription-only have been reclassified as OTC. In fact, in the past 20 years, more than 600 products have made this switch.

Many Products, Few Ingredients

A huge number of OTC products are currently available—more than 100,000 in 2002. However, a relatively small number of common active ingredients are used in these medications. Nearly all of the combination products created to treat pain and other symptoms associated with the common cold, the flu and allergies contain one or more of the following types of active ingredients: a decon-

gestic and an expectorant. The most common ingredient in these products is a decongestant, and the most common combination of ingredients is a decongestant, an antihistamine and an analgesic (Table 1).^{3,4}

Table 1

Active Ingredients in Common OTC Analgesic and Cough and Cold Medications

Active ingredients

- 74 percent have a *decongestant*
- 52 percent have an *antihistamine*
- 45 percent have an *antitussive*
- 40 percent have an *analgesic*
- 20 percent have an *expectorant*

Composition of combination products

- 36 percent have 2 active ingredients
- 30 percent have 3 active ingredients
- 11 percent have 4 active ingredients

Adapted with permission from Agrawal M. OTC cold, cough and allergy products: more choice or more confusion? *J Hosp Marketing* 1999;13:79-86

Mechanisms of Action of Common OTC Products

This section briefly reviews the principal mechanisms of action of some of the most common active ingredients found in OTC pain relievers and products used to treat symptoms of the common cold, the flu and allergies.

Pain Relievers

Three types of pain relievers are used in OTC products: salicylates (of which aspirin is the most widely used); propionic acid derivatives (ibuprofen [Advil, Menadol, Motrin], naproxen sodium [Aleve], ketoprofen [Orudis KT]), and aminophenols (of which only acetaminophen [Panadol, Tempra, Tylenol] is widely used as a pain reliever).⁵ Table 2 gives dosages for these OTC pain relievers.

The therapeutic effects of aspirin and the propionic acid derivatives, also known as the non-steroidal anti-inflammatory drugs (NSAIDs), result from the inhibition of prostaglandin synthesis. Prostaglandins, which regulate many homeostatic processes, are produced locally at sites of tissue injury, where they sensitize nerve endings to painful stimuli and also produce inflammation.⁶ In the central nervous system (CNS), prostaglandins and similar substances (collectively referred to as prostanoids) regulate sleep, body

temperature and pain. There are several different types of prostaglandins, but they are all synthesized from a common precursor (arachidonic acid) by the cyclooxygenase (COX) enzymes. NSAIDs inhibit the enzymatic activity of COX, preventing the synthesis of prostaglandins.

Acetaminophen relieves pain and reduces fever, but has little or no anti-inflammatory effect. The precise mechanism by which acetaminophen produces analgesia is not well understood. It has long been known that it inhibits the synthesis of prostaglandins in the CNS.⁷ Acetaminophen is thought to have little or no effect on the activity of COX or the production of prostaglandins in the peripheral tissues, although it has been suggested that the drug may affect a subtype of the COX enzyme that is distinct from the subtypes that are inhibited by the NSAIDs.⁸ Because of its relative lack of effect on COX in peripheral tissues such as the kidneys or gastrointestinal (GI) tract, acetaminophen is less likely than the NSAIDs to cause adverse renal or GI effects. Even among patients who have consumed very large doses of acetaminophen, few cases of acute renal failure have been reported.⁹ For this reason, acetaminophen is considered an alternative to aspirin or NSAIDs for patients who are at risk of renal side effects.

Table 2
Dosages for OTC Analgesics

Drug	Daily dosage	Maximum daily dosage
Acetaminophen (Panadol, Tempra, Tylenol)	Adults: 325 to 1,000 mg every 4 to 6 hours Children >6 months: 10 to 15 mg/kg every 4 to 6 hours	Adults: 4,000 mg Children: Not to exceed 5 doses/24 hours
Aspirin	Adults: 325 to 650 mg every 4 hours as needed Children >2 years: 10 to 15 mg/kg every 4 hours	Adults: 4,000 mg Children: 60 to 80 mg/kg
Nonsteroidal anti-inflammatory drugs (NSAIDs)		
Ibuprofen (Advil, Menadol, Motrin)	Adults: 200 to 400 mg every 4 to 6 hours Children with baseline temperature $\leq 102.5^{\circ}\text{F}$: 5 mg/kg every 6 to 8 hours Children with baseline temperature $> 102.5^{\circ}\text{F}$: 10 mg/kg every 6 to 8 hours	Adults: 1,200 mg Children: 40 mg/kg
Ketoprofen (Orudis KT)	Adults: 12.5 to 25 mg every 4 to 6 hours	75 mg
Naproxen sodium (Aleve)	Adults: 200 mg every 8 to 12 hours, or initial dose of 400 mg followed by 200 mg 12 hours later	600 mg

⁵ Adapted with permission from APhA drug treatment protocols: self-care of self-limited pain. *J Am Pharm Assoc.* 1999;39:321-30.

Antihistamines

Histamine is an inflammatory mediator that is associated with fatigue, itching, irritation of the nasal passages, sneezing and the production of nasal mucus. Histamine acts by binding to and stimulating histamine H_1 receptors found on nerve endings, smooth muscle cells and glands.¹⁰ Besides blocking the H_1 receptors and preventing histamine from stimulating them, the first-generation antihistamines also exert anticholinergic or serotonergic effects, as well as local anesthetic and sedative effects.¹¹ Commonly used OTC antihistamines include diphenhydramine (Benadryl Allergy, Banophen, Diphenhist), brompheniramine (Dimetapp Allergy) and chlorpheniramine (Aller-Chlor, Chlo-Amine, Chlor-Trimeton Allergy). While these drugs are commonly used in combination

cough and cold medications, their usefulness in the treatment of upper respiratory infections (URIs) is limited to relieving rhinorrhea.

Decongestants

Only one oral decongestant, pseudoephedrine (Allermed, Genaphed, Sudafed), is currently approved by the FDA. Pseudoephedrine is an alpha-adrenergic agonist. It acts on adrenergic receptors in the blood vessels of the nasal mucosa to produce vasoconstriction, resulting in decreased blood flow and shrinkage of tissue in the nasal passages.¹²

Cough Medications

Cough medications are classified as antitussives and expectorants. Antitussives, such as dextromethorphan (Drixoral, Pertussin CS, Robitussin Pediatric) or codeine, work by directly affecting CNS sites that regulate the cough reflex. Only one expectorant, guaifenesin (Guiaatuss, Robitussin, Tusibron), is used in OTC products. It is thought to thin bronchial secretions and make coughing more productive, although these effects are not well supported by the medical literature.

Potential Adverse Events

Side Effects

OTC medications possess a low risk of side effects when used at therapeutic doses. When used occasionally by healthy adults, serious negative side effects are not a major issue. That said, these drugs are not risk free. Certain subsets of patients, such as the very young, the elderly, those with impaired renal function and those taking multiple medications, are at an increased risk of injury caused by OTC pain relievers, antihistamines, the decongestant pseudoephedrine, and antitussives and expectorants.

Pain Relievers

Aspirin and the NSAIDs

On the whole, intolerable side effects caused by aspirin are unusual, and the drug is well tolerated by the vast majority of patients who use it. Several side effects have been reported, however, including cardiovascular effects (dysrhythmias, hypotension, tachycardia), fluid and electrolyte imbalances, and hearing loss or tinnitus.¹³ These effects are dosage-related and are more common at the high dosages used to produce anti-inflammatory effects than at the dosages usually used for relief of transient symptoms.¹⁴ The principal hazard with aspirin is GI irritation and bleeding, and it is for this reason that the newer NSAIDs have largely taken over aspirin's one-time role as the OTC analgesic of choice.

As discussed previously, aspirin and NSAIDs relieve pain and inflammation by inhibiting the production of prostaglandins. Prostaglandins are responsible for regulating physiologic processes important to the health of the gastric mucosa, such as maintaining the protective mucous layer and regulating pH, the secretion of bicarbonate and the flow of blood to the tissues.¹⁵ By inhibiting these processes, aspirin and NSAIDs can produce a variety of gastrointestinal complications, ranging

from relatively mild dyspepsia to more severe problems such as gastrointestinal hemorrhage. Although the risk of serious adverse events for an individual patient is generally small, the large number of people who use these pain medications on a regular basis implies that many potentially serious adverse events occur each year. With respect to ibuprofen, the probability of GI bleeding or ulceration is proportional to the dose taken and especially to the duration of treatment. Gas-tropathy can happen with OTC doses of ibuprofen, although it is not likely in less than two weeks of treatment. GI effects are more likely to occur in older people. Ketoprofen and naproxen sodium, though less studied than ibuprofen, are associated with a higher risk of side effects than placebo.¹⁶

In a recent study of the factors that contribute to GI bleeding, use of OTC NSAIDs was identified as a significant risk factor.¹⁶ For study participants who used an OTC NSAID (aspirin, ibuprofen, naproxen sodium), the risk of GI bleed was about three times as high as it was for those who did not. When data from this study were statistically adjusted for a number of other risk factors, such as age, sex, alcohol use, previous GI bleed and the presence of dyspepsia, the odds of GI bleed in patients who used aspirin or ibuprofen increased as the daily dosage increased.

Aspirin and NSAIDs are also associated with the formation of esophageal strictures.¹⁷ In one small study (n = 79), patients undergoing endoscopy for gastroesophageal reflux disease (GERD) were considered to be NSAID users if they used these medications at least twice a week for a period of at least six months before endoscopy. Those who had strictures that required dilation were significantly more likely to be NSAID users (63.6 percent) than those who had strictures that did not require dilation (26.1 percent). This was true even for those who were

taking low-dose aspirin daily. These findings suggest that regularity of NSAID exposure is a stronger predictor of stricture formation than dosage.

Several factors are associated with an increased risk of NSAID-induced gastropathy:¹⁸

- Age
- Daily NSAID dosage
- History of prior ulcer, GI hemorrhage, dyspepsia and/or previous NSAID intolerance
- Use of corticosteroids
- Use of anticoagulants
- Poor general health

Even low-dose aspirin, which is often used to help prevent cardiovascular disease, may be associated with a significant risk of adverse GI effects in certain patients. In one study, those who used aspirin were two to three times as likely to be hospitalized for GI bleed as those who did not, and those who used aspirin in combination with other NSAIDs were even more likely to be hospitalized than those who used aspirin alone. The increased risk was similar whether enteric-coated aspirin or non-coated aspirin was used and was observed almost exclusively in patients who were over the age of 60.¹⁹

Individuals who are at high risk of developing NSAID-related gastropathy may benefit from concurrent use of gastroprotective medication. Misoprostol (Cytotec), proton-pump inhibitors such as omeprazole (Prilosec) and high dosages of histamine H₂ receptor antagonists such as famotidine (Pepcid) have all been investigated for the reduction of adverse GI effects of NSAIDs. Misoprostol has been shown to reduce the incidence of ulcers when used prophylactically, although it is expensive and is associated with side effects of its own, especially diarrhea.¹⁸ Proton-pump inhibitors and histamine H₂ receptor antagonists have also been shown to be effective in healing lesions, but only misoprostol reduces complications associated with ulcers.^{20,21}

Topical NSAIDs, which are commonly used to provide pain relief for arthritis and other diseases that cause painful joints, can produce local reactions such as itching, rash and eczema in a relatively small number of individuals. It should be noted that topical application of NSAIDs does result in some degree of systemic absorption and diffusion. Systemic effects such as an increased risk of GI bleeding and renal impairment have been reported, although rarely, with topical NSAID use, and there is little information about the long-term adverse effects associated with these agents.²² A review of topical NSAID use, both acutely (for musculoskeletal pain) and chronically, found that topical NSAID application may produce little therapeutic benefit beyond that produced by placebo; however, it does appear to be associated with a lower risk of systemic adverse effects than oral NSAID use.²³

NSAIDs can produce a number of adverse effects on kidney function and, indirectly, on the cardiovascular system.⁹ The renal effects of NSAIDs can vary from mild peripheral edema to irreversible renal damage or renal failure, which are less common. Under normal circumstances, the production of prostaglandins plays a relatively minor role in kidney function, but prostaglandin synthesis becomes more important under conditions of increased renal stress. By inhibiting prostaglandin synthesis, NSAIDs can disturb electrolyte balance, can cause vasodilation and can cause the release of renin (which exerts a number of effects including production of aldosterone and increases in potassium secretion, blood pressure and renal perfusion). Some clinical manifestations of the effects of NSAIDs on kidney function include edema and weight gain. Signs of acute kidney failure include elevated serum creatinine, blood urea nitrogen, serum potassium and weight gain. Other conditions such as nephrotic syndrome with acute interstitial nephritis or renal papillary necrosis have been reported but are quite rare with normal NSAID use. Like aspirin, NSAIDs may also exacerbate hypertension or interfere with the effectiveness of blood pressure medications, although NSAIDs do not appear to elevate blood pressure in normotensive individuals.

There have also been reports of hepatic injury with aspirin or nonsalicylate NSAID use. The risk of this type of injury is thought to be low for most individuals, but it is greatest for those who take high doses of aspirin, especially if there is pre-existing liver disease, juvenile arthritis or rheumatic fever.⁵

Acetaminophen

The long-term use of high dosages of analgesics, especially combination products that also contain caffeine or codeine, can cause a specific form of renal disease known as analgesic nephropathy.²⁴ This disease is characterized by renal papillary necrosis and chronic interstitial nephritis. It is different from NSAID-related renal toxicity, which is associated with acute renal failure. Analgesic nephropathy is a chronic, progressive disorder that develops with years or decades of analgesic use. It appears to require daily consumption of analgesics for a period of at least five years. It was initially attributed to the use of the analgesic phenacetin, which was withdrawn from the market in the United States and other countries in the 1980s. However, it has also been observed with acetaminophen and aspirin, especially when the two drugs are used in combination. Symptoms of analgesic nephropathy include headache, malaise, weight loss, flank pain and dyspepsia. Signs

include hypotension, mild proteinuria and impaired urinary concentration.

Analgesics and caffeine may exert direct toxic effects on kidney cells. In one study that examined the effects of aspirin, NSAIDs, acetaminophen and caffeine, either alone or in combination, on renal medullary cells in a cell culture system, all of these drugs were directly toxic to cultured renal inner medullary cells.²⁵ The combination of acetaminophen and caffeine produced a large synergistic effect, a finding that seems to fit well with the role of caffeine-containing products in the risk of analgesic nephropathy. This effect did not appear to be caused by COX inhibition, because the concentration of drugs required to produce toxicity was an order of magnitude greater than the concentration required to completely inhibit the enzyme. The effect of analgesic exposure appeared to be primarily limited to a small number of rapidly dividing cells, which may explain why analgesic nephropathy appears only after a long period of exposure at high concentrations. Finally, drug concentrations in this study were comparable to those that might be observed in the kidneys of persons taking high doses of medication.

Although these studies show that analgesic use can have adverse effects on renal function under some circumstances, one large, long-term prospective study suggests that even long-term exposure to moderate levels of NSAIDs or acetaminophen does not significantly affect kidney function in most individuals.²⁶ The ongoing Physicians' Health Study, which includes more than 11,000 healthy male physicians, has examined the effects of aspirin, NSAID and acetaminophen use over a period of 14 years. After adjustments were made for changes in renal function with age, no significant effect on creatinine level or creatinine clearance was observed as a function of NSAID or acetaminophen use, even among subjects who consumed the most medication (an average of three to four pills per week over the 14-year period). Nor was renal function affected among the oldest participants, who might have been expected to be at the greatest risk. The results of this study underscore the fact that for the large majority of normal users of pain relievers, these agents can be used safely and are not likely to produce clinically significant effects on renal function. However, it should be noted that the subjects in this study were, in the aggregate, in significantly better health than a true cross section sample of American men of the same age. A more recently published epidemiologic study found an association between the long-term use of acetaminophen or aspirin and chronic renal failure.²⁷ In this study, all of the patients had pre-existing renal or systemic disease. This may explain

in part why this study produced different findings than those of the Physicians' Health Study.

Acetaminophen use is associated with much lower risk of GI effects, including GI bleed, presumably because the drug has little effect on prostaglandin synthesis.^{15,16}

Antihistamines and Pseudoephedrine

First-generation antihistamines are especially sedating and can significantly impair a person's ability to drive and operate machinery—in some cases even more so than alcohol at a blood alcohol concentration level of 0.1 percent. In one study, participants took the recommended adult dosage (50 mg) of diphenhydramine and then completed driving simulation tests.²⁸ Drivers' self-ratings of drowsiness were only weakly correlated with their driving performance, suggesting that individuals who use antihistamines may not be aware that their performance is being affected. Use of antihistamines is often discouraged among the elderly because of an increased risk of falls. All antihistamines can cause dryness of the mouth or eyes.

The decongestant pseudoephedrine, in oral formulations, is associated with side effects related to CNS activation, including nervousness, dizziness and sleeplessness. It can also cause appetite suppression, palpitations, increased blood pressure, hyperglycemia, increased intraocular pressure in persons with narrow-angle glaucoma and urinary retention.¹² In very young children, pseudoephedrine should be used with extreme caution, if at all, because the range between therapeutic and toxic dosages is very narrow. When used by women during the first trimester of pregnancy, this drug is associated with an increased risk of infant gastroschisis (abdominal wall defect).

Antitussives and Expectorants

The most common side effects of codeine when used as an antitussive are nausea, vomiting, sedation and constipation. With dextromethorphan, sedation and GI disturbances are less common, but patients may experience confusion, excitation, nervousness and irritability.²⁹ At high dosages, guaifenesin can cause nausea, vomiting, dizziness, headache, rash and abdominal pain.

Drug-Drug Interactions

A large number of drug-drug interactions are theoretically possible with OTC products. When drugs are used in combination, the pharmacokinetic characteristics (absorption, metabolism, elimination) and the pharmacodynamic properties (effects on target tissues, increasing or decreasing the impact of the medication) are altered, and the likelihood of side effects for each drug may increase.

Table 3 lists drug-drug interactions of common OTC analgesics and cough and cold medications.

Pain Relievers

Several potential interactions between aspirin and other medications have been identified, although for most patients few of these are of clinical significance.^{13,14} Interactions with the greatest clinical significance include those with antihypertensives including angiotensin converting enzyme (ACE) inhibitors and beta blockers. When aspirin is used with anticoagulant agents such as heparin or warfarin (Coumadin), there is an increased risk of bleeding. Aspirin displaces valproate (Depacon, Depakene, Depakote) and phenytoin (Dilantin)

from plasma proteins, causing an increase in the plasma concentrations of these drugs. It causes a decrease in the renal clearance rate of methotrexate, which can result in bone marrow toxicity, with the greatest risk among the elderly or those with renal impairment. The effects of aspirin on renal prostaglandin production can decrease the effectiveness of diuretics. Aspirin can also render oral hypoglycemic and uricosuric agents less effective. Finally, because of the increased risk of GI bleeding and impaired renal function, aspirin should be avoided if nonaspirin NSAIDs are also being used.

NSAIDs other than aspirin are associated with a number of drug interactions that are of potential clinical significance.³⁰ NSAIDs can potentiate the

anticoagulant effect of warfarin, and they can reduce the renal clearance of digoxin (Digitek, Lanoxin) and cyclosporine (Neoral, Sandimmune, SangCya), resulting in increased serum levels. Ibuprofen and naproxen sodium have been shown to reduce the rate of renal clearance of lithium, causing increased serum levels and the potential for toxicity. The effects of NSAIDs on prostaglandin synthesis can significantly interfere with the effects of many different types of antihypertensive medications, including diuretics, beta blockers, ACE inhibitors, vasodilators, central alpha-agonists and peripheral alpha antagonists.⁹

Acetaminophen is associated with few medication interactions that are of clinical significance. The most significant is the potentiation of bleeding and an increase in the international normalized ratio (INR) when used concomitantly with warfarin. This likely reflects a decrease in the hepatic metabolism of warfarin and is possible even at relatively low daily doses of acetaminophen (1500 to 2000 mg per day).³¹ Patients who are taking warfarin should be advised to use the lowest possible dose of acetaminophen, and, as with all patients who are taking warfarin, the INR should be monitored regularly. When acetaminophen dosage is changing, the INR should be monitored with extra

Table 3

Drug-Drug Interactions of Common OTC Analgesics and Cough and Cold Medications

OTC drug	Prescription drug	Effect of interaction
Acetaminophen (Panadol, Tempa, Tylenol)	Warfarin (Coumadin)	Potentiates anticoagulant effect
Nonsteroidal anti-inflammatory drugs (NSAIDs)	Warfarin	Potentiates anticoagulant effect and increases risk of GI irritant effects
	Cyclosporine (Neoral, Sandimmune, SangCya)	Inhibits renal function
	Antihypertensives	Decreases hypotensive response to thiazides, beta blockers, and vasodilators
Ibuprofen (Advil, Menadol, Motrin), naproxen sodium (Aleve)	Digoxin (Digitek, Lanoxin) and lithium	Reduces renal clearance, leading to increased serum levels and toxicity
Aspirin	Antihyperglycemic agents	Potentiates hypoglycemic effect
	Phenytoin (Dilantin), valproic acid (Depacon, Depakene, Depakote), methotrexate	Interferes with renal clearance and protein binding, leading to increased drug levels
Antihistamines		
Brompheniramine (Dimetapp Allergy), chlorpheniramine (Aller-Chlor, Chlo-Amine, Chlor-Trimeton Allergy), diphenhydramine (Benadryl Allergy, Banophen, Diphenhist)	Benzodiazepines, barbiturates, opioids, phenothiazines	Potentiates central nervous system depressant effects
Decongestant		
Pseudoephedrine (Allermed, Genaphed, Sudafed)	Antihypertensives	Antagonizes antihypertensive effects, and produces hypertensive crises and cardiac arrhythmias with monoamine oxidase inhibitors (MAOIs)

Adapted with permission from Hong PK, Gillespie BK. Drug interactions between prescribed and over-the-counter medication. *Drug Safety*. 1995;13:296-303.

vigilance. The antibiotics rifampin and isoniazid also inhibit the metabolism of acetaminophen by the liver, and an increased risk of hepatotoxicity has been reported when acetaminophen is used in combination with these medications.^{32,33}

Antihistamines, Pseudoephedrine and Antitussives

These ingredients, common in many cough medications, have important interactions with a number of other drugs, including antihypertensives,

antidepressants and monoamine oxidase inhibitors (MAOIs). Pseudoephedrine can inhibit the effects of antihypertensive medications and can produce hypertensive crises and cardiac arrhythmias when combined with MAOIs.³⁰ Additionally, when it is combined with stimulants, its CNS effects can be increased.³⁴ Medication interactions with OTC antihistamines include the potentiation of the CNS depressant effects of benzodiazepines, barbiturates, opioids and phenothiazines.

Alcohol and OTC Medications

Pain Relievers

When combined with NSAID use, even minimal alcohol use (more than one alcoholic beverage per week) has been associated with an increased risk of GI bleeding.¹⁶ When alcohol use intensifies to the point of abuse, use of the NSAIDs naproxen sodium and ibuprofen significantly increases this risk, sometimes by as much as three times the risk of individuals who have no history of alcohol abuse.³⁵

Acetaminophen is much less likely than NSAIDs to be associated with intestinal bleeding, ulceration or other GI complications. However, a form of acute, sometimes fatal liver failure may occur in persons who consume moderate to large amounts of alcoholic beverages regularly and concurrently take acetaminophen. Presently available research evidence does not provide complete information about this clinical phenomenon, and controversy exists as to whether standard doses of acetaminophen can initiate it.^{36,37} Attempts to study the interactive effects on the liver of acetaminophen and alcohol (by short-term administration of the maximal daily dose of acetaminophen under controlled conditions to patients with alcoholism) have not shown evidence of liver injury.³⁷ There appears to be a consensus that alcoholics frequently take this drug in excessive doses and that doing so puts them at markedly increased risk for liver damage. Agreement also exists that acetaminophen at standard doses is a safer analgesic for

these individuals than an NSAID agent would be.³⁸

As a practical matter, it is probably reasonable for physicians to allow their alcohol-using patients to take up to 4 g of acetaminophen daily but it is important to discourage higher dosages.

The FDA now requires that a warning about the use of alcohol be printed on the package of all OTC pain relievers. This warning advises individuals who consume three or more alcoholic beverages per day to consult with a physician before using these medications. When counseling these patients, physicians should do their best to explain (1) that the combination of alcohol and aspirin or NSAIDs poses a risk of GI bleeding and (2) to minimize the risk of serious liver injury, it is critically important never to take more than the recommended dose of acetaminophen.

Antihistamines, Pseudoephedrine and Antitussives

Data regarding the effects of alcohol use while taking antihistamines, pseudoephedrine or antitussives is limited. However, it is known that the OTC antihistamines increase the sedative and psychomotor effects of alcohol and that these effects are more pronounced in elderly people. Additionally, alcohol amplifies the drowsiness, sedation and impaired motor skills associated with opiates such as dextromethorphan and codeine.

Patient Factors in OTC Medication Misuse

As mentioned previously, OTC medications clearly have a place in the management of many mild ailments and, when used appropriately, can save physicians and patients time and money that would be better spent on more important problems. However, there are some patient-related obstacles to appropriate use. These include:

- A perception among patients and parents that OTC medications are not “real” medicine;
- A lack of understanding about the ingredients in combination products;
- An inability to read and/or understand product labeling and to calculate and measure the proper dose;

- Discrepancies in reporting all medication use to the physician;
- An inability to accurately self-diagnose; and
- Unrealistic expectations about the normal range and duration of symptoms associated with the common cold, the flu and allergies, and about the ability of any medication to attenuate those symptoms.

Real Medicine

Two factors likely influence the misperception among patients that OTC medications are somehow less effective and/or potentially less dangerous than prescription medications. First, of course, the fact that anyone can buy any quantity of OTC drugs without consulting a physician makes them seem benign in comparison to the range of prescription drugs that are unavailable without a physician's written permission. Second, the number of distribution outlets for OTC medications has increased in the past 20 to 30 years. Groceries and discount stores carry OTC medications as a convenience to their customers, and they may not even employ a pharmacist to help patients choose appropriate medications. The mere availability of OTC medications alongside milk, bread and cereal may contribute to a false sense of safety among patients. It should also be noted that patients often make decisions about which products to use on the basis of advice and information that they gather from many sources, such as friends, family, magazines, the Internet and television. While this information is easily accessed, it is not always entirely accurate, and it cannot give patients all the information they need to make a decision about how well suited a product is for their condition.

Obviously, if patients do not consider that OTC medications carry a risk of adverse events, they may adopt a somewhat cavalier attitude toward these products. Patients and parents may take or administer larger doses or may do so more frequently than recommended. It has been documented that patients knowingly use OTC medications in a manner that is inconsistent with product labeling.⁵ Commonly, patients use a larger-than-recommended dosage of OTC medications with the goal of improving symptom relief beyond what they perceive the recommended dose will confer. Unfortunately, patients may be using certain physician behaviors as rationale for this "more is better," or at least "more is not any riskier," attitude. For example, physicians accustomed to prescribing ibuprofen in strengths of 600 mg to 800 mg per dose may tell patients that they can take three or four OTC-strength doses for the same effect. This advice about ibuprofen is relatively safe in young healthy patients who have an acute need

for analgesia. However, patients may take away the message that it's safe to take three or four OTC-strength doses of all OTC medications. In the case of pain relief products, the increased risk of adverse events generally outweighs any incremental pain relief that might result from a higher dose.

Additionally, patients may not adequately appreciate that use of an OTC medication can increase the risk of a drug-drug interaction if they are taking prescription medications, perhaps for a chronic condition. Finally, patients may take OTC drugs without regard to their alcohol consumption.

Understanding Combination Products

As mentioned previously, many OTC medications combine two to five active ingredients. Understandably, many patients choose products based on the symptoms they want to relieve, and they may not realize that a combination product they are taking contains one or more active ingredient(s) that they might also be taking in the form of another OTC or prescription medication. Additionally, patients tend to think of OTC medications in terms of brand names (e.g., Nyquil, Tylenol, Excedrin, Bayer, Motrin) and not in terms of the active ingredients. A practice tool that may help patients avoid inadvertently taking too much of a particular medication is a list of common brand-name products and their active ingredients (see *Know What's in the Medicine You Take*).

Following Dosing Recommendations

Obvious impediments to taking or administering OTC medications properly are poor vision, poor comprehension of the English language³⁹ and a lack of understanding about how to calculate a dose. In one study, parents or caregivers were asked to calculate and then administer a correct dose of acetaminophen for their children. Only 30 percent were able to determine the correct dose and properly administer it.⁴⁰ When discussing the use of OTC medications with a patient or a parent, the physician should specifically address several important points. These include: the reason for taking the medication; the dosage at which it should be taken; the frequency of administration; the anticipated effect of the medication on symptoms; and side effects that the patient might expect.³⁰ Parents should be educated about the practice of calculating dosages based on the child's weight and they should understand the differences between pounds and kilograms, teaspoons and milliliters (see *Medicine and Your Child: How to give the right dose*).

Discrepancies in Reporting Medication Use

Physicians do not always know about their patients' medication use, even when the patients

are using a large number of OTC products.⁴¹ In addition, there are often discrepancies between medications that have been prescribed by the physician or recorded in the patient's chart and those that the patient is actually using. In one study of such discrepancies and the factors that contribute to them, the most common discrepancy was related to the patient's failure to tell the physician about the medications the patient was taking.⁴¹ Failure to take a recommended medication and taking a different dosage than had been recommended were also issues. Increasing patient age and increasing number of medications used were both independent predictors of an increased likelihood of discrepancy. About one-third of the discrepancies noted involved OTC products.

Missing the Diagnosis

Research data suggest that many people who have pain of limited duration (less than two weeks) and/or symptoms associated with the common cold, the flu and allergies can accurately identify their symptoms and choose OTC products appropriately.⁴² However, some may misattribute symptoms of a serious disease to something more benign.³⁹ For example, a patient with intermittent mild chest pain may decide that arthritis, not heart disease, is causing his symptoms, or a patient who has symptoms of fungal vaginitis, which can mimic

those of more serious disorders, may self-treat for months using an OTC antifungal preparation. The risk here is twofold: Patients may expose themselves unnecessarily to adverse drug events associated with OTC medications, and appropriate treatment for the actual disease or disorder may be delayed. Helping patients understand when to consult their physician and when they may reasonably be able to diagnose and treat a mild and self-limited condition on their own is key to helping them use OTC medications appropriately.

Managing Expectations

Patients and parents seeking occasional analgesia and relief from other symptoms associated with the common cold, the flu and allergies may not be aware of the range, duration and severity of symptoms that are considered normal. They may be expecting an OTC product to relieve all of their symptoms in 24 hours, or they may expect that an OTC medication will restore their child to baseline with one dose. It is not possible for the physician to predict the exact course or duration of any malady for which the most common OTC medications are used. However, helping patients and parents understand what is typical may go a long way in managing their expectations of a mild illness and of the medications they use to treat it (see *Timeline of Symptoms Associated with the Common Cold*).

OTC Products and Special Patient Groups

Many patient groups may be particularly susceptible to adverse events that are caused by OTC products. They include children, the elderly, pregnant and breastfeeding women, and patients with pre-existing conditions.

Children

Parents often have questions about the best way to manage pain, fever and other symptoms associated with the flu, the common cold and allergies in children. While some parents are reluctant to give their children any medication, physicians can reassure them that, when used appropriately, OTC pain relievers pose very little risk and can improve quality of life for both the child and the parents. In terms of pain relief, acetaminophen and ibuprofen are the most often recommended, and recent reviews have suggested that acetaminophen should be considered first-line treatment in pediatric patients.⁴³⁻⁴⁵ The use of aspirin should be avoided in children under the age of 18 because of the risk of Reye's syndrome.

There are fewer data available on the safety and efficacy of ibuprofen use in children, but one

recent randomized trial showed that among very young children (less than two years of age) who received either acetaminophen or ibuprofen for fever, the risk of serious adverse events was small and did not vary by medication choice. Some suggest that ibuprofen be avoided in children who are dehydrated. Allergic responses have been reported when ibuprofen is used by children who are allergic to aspirin or who have asthma. As with any medication, parents should be alerted to symptoms that suggest an allergic reaction, such as hives, shortness of breath or facial swelling, and instructed to discontinue the use of ibuprofen and contact a physician immediately if these symptoms are noted. They should also be encouraged to initiate and maintain clear communication with the child's other caregivers to minimize the risk of inadvertent "double dosing." One tool to facilitate such communication and enable documentation of a child's medication history is a medication log (see *Keeping Track of Your Child's Medicine*).

Fever itself rarely requires treatment and, with rare exceptions, is not harmful to the child.⁴⁵

Parents should understand that a temperature as high as 101°F should not be considered dangerous and that other means of lowering the child's temperature (e.g., clear liquids, a tepid bath) may help without the need to use medication.

Pseudoephedrine has been associated with hallucinations, hypertension and dystonic reactions when used in children and can also cause irritability and hyperactivity.²⁹ OTC medications containing pseudoephedrine are available for very young children, but because the range between therapeutic and toxic dosage is very narrow in this group, decongestants should be used with extreme care, if at all. Narcotic antitussives such as codeine are not recommended in young children and are reported to have caused fatalities, especially when used in infants.²⁹

Elderly Patients

Use of OTC medications can complicate the medical treatment of older patients in a number of ways. In many cases there is little data about the response of older individuals to medications because the elderly are often excluded from clinical trials. Elderly patients who do participate in clinical trials may be unusually healthy in comparison with the elderly population in general and may not be representative of older patients seen in actual clinical practice. Perhaps the most important aspect of this patient group in regard to OTC medications is its use of prescription medications with which an OTC medication might interact. The elderly fill an average of 30 prescriptions per year for an average of about seven different drugs. On the other hand, published data suggest that elderly persons are less likely to use OTC medications, and that they read drug labeling more completely and ask for help from their pharmacist more often than younger persons.⁴¹

One particular concern about OTC use among elderly patients is the risk of side effects associated with the NSAIDs.⁴⁶ In this subset of patients, the NSAIDs are associated with a relatively high risk of renal disease and GI bleeding.⁴⁷

The decongestant pseudoephedrine can be dangerous in elderly patients because it can elevate blood and intraocular pressure and can worsen existing urinary obstruction. Also, the list of drugs with which pseudoephedrine is likely to have an adverse interaction is long. It includes beta blockers, indomethacin (Indocin), methyldopa (Aldomet), tricyclic antidepressants, insulin and oral hypoglycemic agents. Finally, this drug should not be used in anyone taking an MAOI or medication for seizure disorder.

Care should also be taken with the first-generation antihistamines in elderly patients. Sedative and

anticholinergic effects can be troublesome and may be enhanced because of the older patient's diminished capacity for drug metabolism. There is little published data regarding the use of OTC antitussives and the expectorant guaifenesin among elderly patients, but dextromethorphan should not be used by anyone who is taking an MAOI.

Pregnancy and Breastfeeding

Analgesia during pregnancy is generally limited to acetaminophen, which is considered safe for short-term use. Aspirin is to be avoided in pregnant women. It carries the risk of anemia, ante- or post-partum hemorrhage, and prolonged gestation and labor for the mother and low birth weight for the infant. Use of other NSAIDs, such as ketoprofen and naproxen sodium, especially during the third trimester, is not recommended. These drugs are associated with adverse effects in the fetus, such as constriction of the ductus arteriosus, tricuspid incompetence and pulmonary hypertension.

While the first- and second-generation antihistamines are generally considered safe during pregnancy, their use should be avoided during the first trimester.⁴⁸ Likewise, pseudoephedrine should be avoided during the first trimester because of an increased risk of infant gastroschisis (abdominal wall defect).

The American Academy of Pediatrics (AAP) has developed a set of guidelines for the use of many prescription and nonprescription medications by nursing mothers. These guidelines are available online at <http://www.aap.org/policy/0063.html>. In general, acetaminophen and the NSAIDs are considered safe for use while a woman is breastfeeding. The first-generation antihistamines do pose a theoretical risk to the infant, especially the newborn and the premature infant, but they are used with confidence in clinical situations where benefit outweighs that risk. These drugs are excreted in breast milk, and they may cause side effects in a nursing infant, such as sedation, paradoxical stimulation, irritability, crying, sleep disturbances and refusal to feed. Additionally, these drugs may interfere with milk production. Long-term use should be limited. The FDA recommends that aspirin be avoided by nursing mothers if possible. Salicylates can be excreted in human milk, and the use of high dosages of aspirin by a breastfeeding mother can produce effects in the nursing infant, such as rashes or abnormalities of bleeding or platelet function.¹³ There are no data on the safety of guaifenesin in nursing infants. Some centrally acting antitussives are found in breast milk, but there is very little published data regarding their safety in breastfeeding women.

Although it is true that many OTC preparations contain alcohol, the AAP suggests that the level of alcohol found in most medications does not pose a safety hazard for a nursing infant. In general, the risk of adverse medication events during pregnancy and breastfeeding can be minimized by following these steps:

- Consider alternatives to medication, if possible.
- Avoid use of medications during the first trimester.
- Take oral medications after nursing or before the infant's longest sleep period.
- Avoid the use of extra-strength, maximum-strength or long-acting medications.
- Avoid combination products.
- Watch the child for possible side effects.⁴⁹

Other Patient Groups

A number of special patient populations may be at increased risk of adverse events associated with OTC analgesic use.⁵ These groups are listed in *Table 4*.

- In patients with renal disease, the inhibition of prostaglandin synthesis by NSAIDs may increase the risk of a number of renal effects that rely on prostaglandins. Fluid or electrolyte imbalance, acute interstitial nephritis or even renal failure may result. A number of risk factors have been associated with an increased risk of adverse effects of NSAID use on renal function, including pre-existing renal insufficiency, congestive heart failure, hypertension and liver disease.

- Patients with cardiovascular disease may also be at increased risk of adverse events, both because of the effects of NSAIDs on the kidneys and because of interactions between OTC medications and antihypertensives.

- Patients with diabetes may be more likely to use nonprescription pain medications because of a decreased pain tolerance and also because of alterations in the vascular system caused by diabetes. These indi-

viduals are also at increased risk of renal dysfunction resulting from NSAID use.

- Many individuals who have asthma have severe, and potentially fatal, hypersensitivity

Table 4

Use of OTC Analgesics in Patients with Selected Disease States and Medical Conditions*

<i>Disease State or Medical Condition</i>	<i>Preferred Agent(s)</i>	<i>Use with Caution</i>
Allergy to aspirin, NSAIDs or tartrazine	Acetaminophen (Panadol, Tempra, Tylenol), choline salicylate (Arthropan) or sodium salicylate	Aspirin, ibuprofen, ketoprofen and naproxen sodium
Asthma or nasal polyps	Acetaminophen, choline salicylate or sodium salicylate	Aspirin, ibuprofen, ketoprofen and naproxen sodium
Bleeding disorder	Acetaminophen or nonaspirin salicylates	Aspirin, ibuprofen, ketoprofen and naproxen sodium
Congestive heart failure	Acetaminophen	Sodium salicylate, effervescent aspirin tablets with a high sodium content, and nonsalicylate NSAIDs
Dysmenorrhea	Ibuprofen (Advil, Menadol, Motrin), ketoprofen (Orudis KT) or naproxen sodium (Aleve)	None
Hepatic impairment	Acetaminophen†	All NSAIDs
Hypertension	Acetaminophen	All NSAIDs
Lactation	Acetaminophen	Salicylates
Lithium therapy	Acetaminophen or aspirin	Ibuprofen, ketoprofen and naproxen sodium
Methotrexate therapy	Acetaminophen	All NSAIDs
Non-insulin-dependent diabetes mellitus managed with first-generation sulfonylureas	Acetaminophen or ibuprofen	Ketoprofen, naproxen sodium and salicylates
Oral anticoagulant therapy	Acetaminophen‡	Aspirin, ibuprofen, ketoprofen and naproxen sodium
Peptic ulcer disease	Acetaminophen	All NSAIDs
Pregnancy	Acetaminophen	All NSAIDs
Renal impairment	Acetaminophen	All NSAIDs
Urticaria	Acetaminophen	Salicylates
Varicella or influenza symptoms in a pediatric patient	Acetaminophen or ibuprofen	Salicylates

* — This table is intended to serve as a guide for the reader; consult professional labeling before making any drug therapy recommendations.

† Patients who have chronic liver disease that is not progressing may use acetaminophen.

‡ Patients taking anticoagulants who also take acetaminophen regularly or at higher doses should be monitored carefully.

NSAIDs = Nonsteroidal anti-inflammatory drugs.

Adapted with permission from APHA drug treatment protocols: self-care of self-limited pain. *J Am Pharm Assoc.* 1999;39:321-30.

reactions to aspirin or nonaspirin NSAIDs. The American Society of Health-System Pharmacists (ASHP) report recommends that patients with asthma avoid the use of most NSAIDs if they have a history of nasal polyps or aspirin-induced disorders including severe rhinitis, sinusitis, urticaria, angioedema, bronchospasm or anaphylaxis. In these patients, acetaminophen, choline salicylate (Arthropan) and sodium salicylate are considered safer alternatives.⁵

- Patients with coagulation defects should avoid the use of NSAIDs; the risk of bleeding complications is lower with nonacetylated salicylates and with acetaminophen, both of which have less effect on platelet function.

- Although patients with gout may use NSAIDs to help relieve pain, these agents inhibit the excre-

tion of uric acid by the kidneys and may worsen hyperuricemia.

- Endurance athletes are another group that may be at increased risk of adverse effects related to OTC use. It has been noted that exercise increases the kidneys' requirement for prostaglandins, and the suppression of prostaglandin production by NSAIDs may explain why some athletes, such as long-distance runners, appear to be at increased risk of renal dysfunction. Continuous heavy exercise, dehydration and heat stress may all make endurance athletes more susceptible to adverse renal effects of analgesics, although one study that compared the effects of acetaminophen, ibuprofen and placebo in healthy young patients under these conditions showed that acetaminophen did not affect renal function.⁵⁰

Herbal Products

A complete discussion of herbal and "alternative" medications, dietary supplements and vitamins is beyond the scope of this monograph. It should be noted, however, that many patients use these products and that there is some potential for them to interact with prescription or OTC medications.⁵¹ A recent review noted that herbal products such as St. John's wort are used by many individuals to self-treat symptoms of depression.⁵² Although these products are not regulated by the FDA, and patients usually perceive them to be very safe, there is a potential for adverse effects. With St. John's wort, there have been reports of induction of manic symptoms, both in individuals with a history of mania and in those with no such history. Data regarding the potential for medication

interactions with herbal preparations are very limited, but St. John's wort has been shown to produce clinically significant increases in the blood concentrations of some medications, including digoxin and the HIV medication indinavir (Crixivan). It has also been noted that estimates of the risk of side effects or drug reactions associated with herbal remedies may be too low because few patients may consult with physicians or pharmacists about their use of the herbal or alternative medications or adverse events that they experience.⁵³ Information regarding herbal and alternative medications, dietary supplements and vitamins can be found in the *Physicians' Desk Reference for Herbal Medicines*.

OTC Use: The Family Physician's Role

Given the abundance of health information readily available to patients in books, on television and on the Internet, and the increasing trend toward self-care, the use of OTC medications is not likely to wane. Yet, relative safety—the very characteristic that makes these products an attractive choice for self-treatment—also makes them potentially quite dangerous. Widespread use of these products means that even rare adverse effects can have a significant impact on public health. Family physi-

cians are especially well positioned to help their patients evaluate these medications and use them safely by regularly asking patients what kinds of OTC products they use and how often, by keeping track of self-reported use and by helping them understand proper dosing for themselves and their children. These conversations can be conducted fairly briefly in the office setting and can be facilitated by the use of take-home tools and educational materials.

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Tools and Information for Patients

Know What's in the Medicine You Take: Active ingredients in common OTC pain relievers and allergy, cough and cold medications

Pain relievers		
	<i>Brand name</i>	<i>Generic</i>
	Panadol, Tempa, Tylenol	Acetaminophen
	Bayer, St Joseph	Aspirin
	Advil, Menadol, Motrin	Ibuprofen
	Orudis KT	Ketoprofen
	Aleve	Naproxen sodium
Single-ingredient allergy and cold products		
	<i>Brand name</i>	<i>Generic</i>
Antihistamines	Dimetapp Allergy	Brompheniramine
	Aller-Chlor, Chlo-Amine, Chlor-Trimeton Allergy	Chlorpheniramine
Antitussive	Benadryl Allergy, Banophen, Diphenhist	Diphenhydramine
	Drixoral, Pertussin CS, Robitussin Pediatric	Dextromethorphan
Decongestant	Allermed, Genaphed, Sudafed	Pseudoephedrine
Expectorant	Guiatuss, Robitussin, Tusibron	Guiafenesin
Combination allergy and combination cold and flu products*		
	<i>Brand name</i>	<i>Generic</i>
	Advil Cold & Sinus, Aleve Cold & Sinus, Bromfed, Chlor-Trimeton 12, Contac, Dimetapp Cold & Flu, Triaminic, Dristan Cold, Theraflu, Alka-Seltzer Plus, Sudafed Plus, Tylenol Cold, Vicks DayQuil	Each of these products contains two or more of the following drugs acetaminophen, brompheniramine, chlorpheniramine, dextromethorphan, diphenhydramine, guaifenesin, ibuprofen, pseudoephedrine

* - This list does not include all combination allergy and combination cold and flu products that might be available.

WEB SITES

Patient-oriented information and brochures may be obtained from the following Web sites:

American Academy of Family Physicians
www.familydoctor.org

American Geriatrics Society
 Patient Education Forum online at www.americangeriatrics.org/education/forum/otcdrug.shtml

American Pharmaceutical Association
www.pharmacyandyou.org

American Academy of Pediatrics and Medem
 Healthcare Information

Children's Health
www.medem.com/medlb/bufferpage_aap.cfm

Consumer Healthcare Products Association
www.chpa-info.org

U.S. Food and Drug Administration
 Center for Drug Evaluation and Research
 Over-the-Counter (OTC) Drugs
www.fda.gov/cder/otc/index.htm

Timeline of Symptoms Associated with the Common Cold

There is no cure for the common cold. Medicine can only make your symptoms less bothersome until your body can fight off the virus. Medicine won't make your cold go away completely. The following are tips to help you feel better when you have a cold.

- Stay home and rest, especially while you have a fever.
- Don't smoke and avoid secondhand smoke.
- Drink plenty of fluids like water, fruit juices and clear soups.
- Don't drink alcohol.
- Gargle with warm salt water a few times a day to relieve a sore throat. Throat sprays or lozenges may also help relieve the pain.
- Use salt water (saline) nose drops to help loosen mucus and moisten the tender skin in your nose.

Many cold medicines are available over-the-counter (without a prescription from your doctor). If you decide to use an over-the-counter (OTC) medicine to treat your cold symptoms, consult the chart below.

Day	Symptoms	OTC Medicine
1	Fatigue, mild sore throat	Acetaminophen (some brand names: Panadol, Tempra, Tylenol) or nonsteroidal anti-inflammatory drug (ibuprofen [some brand names: Advil, Menadol, Motrin])
2	Runny nose	Antihistamine (diphenhydramine [some brand names: Benadryl Allergy, Banophen, Diphenhist], chlorpheniramine [some brand names: Aller-Chlor, Chlo-Amine, Chlor-Trimeton Allergy])
3	"Stopped up" nose	Decongestant (pseudoephedrine [some brand names: Allermed, Genaphed, Sudafed])
4	Dry cough	Antitussive (dextromethorphan [some brand names: Drixoral, Pertussin CS, Robitussin Pediatric])
5 and 6	Moist, productive cough	Expectorant (guaifenesin [some brand names: Guaiatuss, Robitussin, Tusibron])
7	Voice "breaks" or disappears altogether	No medicine will help your voice come back sooner. Resting it is the only thing that will help.

Keeping Track of Your Child's Medicine

A medication log can help you and your child's other caregivers (for example, child care providers or a school nurse) keep track of the medicine your child takes. This information will be useful for your doctor in case there are any problems with the medicine. Keeping track can also help avoid "double dosing," giving too much medicine or giving it too often.

Medication Log for: _____

What kind of medicine did you give your child? Write down the name of the medicine(s) that is/are listed on the package.

At what time did you give it (be specific)? If you gave it more than once during the day, be sure to write down each time.

If you gave your child the medicine for more than one day, write down all the dates and how many times each day.

How much medicine did you give in each dose?

If you talked to a nurse, doctor or pharmacist about this medicine before giving it, what is his or her name and phone number?

Did you notice anything unusual about your child after he or she took the medicine? (Examples might be a rash, difficulty breathing, a headache or other symptoms that your child didn't have before taking the medicine.)

If you do notice anything unusual, stop using the medicine and call the doctor right away.

Phone number of your child's doctor: _____ Phone number of local poison control center: _____

How to Get the Most from Your Medicine

What do I need to know?

Over-the-counter (OTC) medicines can help you feel better. But if they are taken the wrong way, they can actually make you feel worse. To use OTC medicines correctly, follow the guidelines below.

What questions should I ask my doctor about my medicines?

If there is something you don't understand about a medicine you're taking or are planning to take, ask your doctor or pharmacist. If you still don't understand, ask him or her to explain things more clearly. If you are taking more than 1 medicine, be sure to ask how the medicines will work together in your body. Sometimes medicines cause problems when they are taken together (called a drug interaction).

Below is a list of questions you can ask your doctor to learn how to use each medicine correctly and safely:

- What does the medicine do?
- When and how should I take the medicine?
- What side effects (reactions your body may have to the medicine) could I have?
- Will the medicine react to any other medicines, foods or drinks?
- Should I avoid any activities while I'm taking the medicine?
- How will I know if the medicine is working?

Things to know about each medicine you take

- Name (generic name and brand name)
- Reason for taking it
- How much to take and how often to take it
- Possible side effects and what to do if you have them
- How long to continue taking it
- Special instructions (taking it at bedtime or with meals, etc.)

Should I avoid any foods, drinks or activities while I'm taking medicine?

Some foods can cause side effects, such as stomach upset, if you are taking medicine. Drinking alcohol is generally not a good idea while you are taking medicine. Some medicines cause reactions such as sun sensitivity (getting a sunburn or sun rash), so you may have to limit your outdoor activities or protect your skin from the sun.

Read the label to see what to avoid while you are taking an over-the-counter medicine. Follow the instructions just as you would with a prescription medicine. If you have questions, ask your doctor or pharmacist.



Medicine do's and don'ts

- Do read the label carefully.
- Do take your medicine exactly as your doctor tells you to.
- Do make sure that each of your doctors (if you see more than one) has a list of all of the medicines you're taking.
- Do make sure everyone you live with knows what medicine you're taking and when you're supposed to take it.
- Don't combine prescription medicines and OTC medicines unless your doctor says it's OK.
- Don't stop taking a medicine or change how much you take or how often you take it without first talking to your doctor.
- Don't take someone else's medicine.
- Don't use medicine after its expiration date.
- Don't crush, break or chew tablets or capsules unless your doctor tells you to. Some medicines won't work right unless they are swallowed whole.

What's the difference between generic and brand name medicines?

Just like foods, some medicines come in both brand names and generics. Generic medicines are generally cheaper. Compare the list of ingredients. If the generic has the same ingredients as the brand name, you may want to consider using it. But be careful: The generic may contain different amounts of certain medicines. Ask your doctor or pharmacist if you have questions about which medicine to choose.

Tips for choosing medicines

- If you have questions, ask your doctor or pharmacist.
- Although it can seem overwhelming, take the time to look at all the choices.

- Read the label carefully and note what symptoms the medicine will treat.
- Look for a medicine that will treat only the symptoms you have. For example, if you only have a runny nose, don't pick a medicine that also treats coughs and headaches.
- Note how much medicine you should take, and what side effects it may cause.
- Note what medicines or foods you should not take with the medicine.
- Check to see if the medicine causes problems for people with certain health problems (such as asthma or hypertension).

What if I don't feel better even though I'm taking my medicine?

If you're taking an over-the-counter medicine and it doesn't seem to be working, call your doctor. Your sickness can get much worse if you wait too long to get treated by your doctor.

For more information

The Institute for Safe Medication Practices
Phone: 215-947-7797
Internet address: www.ismp.org

National Council on Patient Information and Education
Phone: 301-656-8565
Internet address: www.talkaboutrx.org

This handout provides a general overview on this topic and may not apply to everyone. To find out if this handout applies to you and to get more information on this subject, talk to your family doctor.

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Como Recibir el Mejor Provecho de su Medicine

¿Qué debo de saber?

Las medicinas sin receta médica (SRM) le pueden ayudar a sentirse mejor. Pero si las medicinas no se toman correctamente, incluso le pueden hacer sentir peor. Para usar medicinas sin receta médica (SRM) correctamente, siga las indicaciones de abajo.

¿Qué preguntas debo hacerle a mi doctor acerca de mis medicinas?

Si hay algo que usted no entiende acerca de la medicina que está tomando, pregúntele a su doctor. Si todavía no entiende, pídale a su doctor que le explique las cosas más claramente. Si usted está tomando más de una medicina, asegúrese de preguntar cómo van a trabajar estas medicinas juntas en su cuerpo. Algunas veces las medicinas pueden causar problemas cuando se toman juntas (se llama interacción de drogas).

Hay aquí una lista de preguntas que usted puede hacerle a su doctor para ayudarlo a aprender como usar su medicina correctamente y en una forma segura:

- ¿Qué es lo que esta medicina va a hacer?
- ¿Cuándo y cómo debo de tomar la medicina?

- ¿Cuáles son los efectos secundarios (reacciones que su cuerpo puede tener a esta medicina) que puedo tener?
- ¿Puede mi medicina reaccionar con algún otro medicamento, comidas o bebidas?
- ¿Debería evitar alguna actividad mientras esté tomando esta medicina?
- ¿Cómo voy a saber si la medicina está dando resultado?

Lo que debe saber de cada medicina que está tomando

- Nombre (genérico y nombre de marca)
- Razón por que la está tomando
- Cuánto va a tomar y cada cuánto tiempo
- Cuáles son los posibles efectos secundarios y qué puedo hacer si los tiene
- Qué tiempo debe continuar a tomarla
- Indicaciones especiales (tomar a la hora de acostarse o con las comidas, etc.)

¿Debería evitar ciertas comidas, bebidas, o actividades mientras estoy tomando medicina?

Algunas comidas pueden causar efectos secundarios, como salto de estómago, si usted está tomando medicamentos. El beber alcohol no es generalmente una buena idea mientras está tomando medicamentos. Algunos



medicamentos causan reacciones como sensibilidad al sol (quemadura de sol o salpullido de sol) así que puede que usted tenga que limitar sus actividades al aire libre o tomar precauciones para proteger su piel del sol. Lea la etiqueta para ver lo que debe de evitar mientras está tomando medicinas sin receta médica (SRM). Siga las instrucciones justo como lo haría con sus medicinas con receta. Si tiene preguntas, hágalas a su doctor o farmacista.

Los sí y los nos de la medicina

- Lea las etiquetas cuidadosamente.
- Tome la medicina exactamente como su doctor le ha dicho.
- Asegúrese que cada 1 de sus doctores (si tiene más de 1) tiene una lista de las medicinas que está tomando.
- Asegúrese que su familia o su compañero de cuarto saben que medicina está tomando y cuando se supone que la debe tomar.
- No combine ninguna medicina con receta y medicina sin receta (SRM) a no ser que su doctor le diga que está bien.
- No pare de tomar la medicina o cambie la cantidad y la frecuencia que la toma sin antes hablar con su doctor.
- No tome la medicina de otra persona.
- No utilice el medicamento después de la fecha de expiración.
- No triture, rompa ni mastique tabletas o pastillas a no ser que su doctor le diga a hacerlo. Algunas medicinas no funcionan si se las tragan enteros.

¿Cuál es la diferencia entre la medicina genérica y la de marca?

Así como en los alimentos, algunas medicinas vienen en ambos nombres: genéricos y de marca. Las medicinas genéricas son generalmente más baratas. Compare la lista de ingredientes. Si la genérica tiene los mismos ingredientes como la medicina de marca,

usted quizás quiera considerar usarla. Pero sea cuidadoso: el genérico puede contener diferentes cantidades de ciertos medicamentos. Pregúntele a su doctor o farmacista si tiene preguntas sobre cuál medicina escoger.

Consejos para escoger medicinas

- A pesar que parece abrumador, tome el tiempo de mirar a todas sus elecciones
- Lea las etiquetas cuidadosamente y note qué síntomas puede tratar esa medicina.
- Busque una medicina que te va a tratar sólo los síntomas que tiene, Por ejemplo, si solamente tiene nariz que escurre, no escoja la medicina que trata tos y dolores de cabeza.
- Vea cuánto medicamento debe tomar y que efectos secundarios puede causarle.
- Note cuáles medicinas o alimentos no se deben tomar con la medicina.
- Compruebe si la medicina ocasiona problemas a personas con ciertos problemas de salud (como el asma o la hipertensión).

Si está intentando tratarse con medicinas sin receta médica (SRM) y parece que no está dando resultado, llame a su doctor. Su enfermedad puede empeorar si demora vd. demorado antes de ser tratado por su doctor.

Este panfleto provee un resumen del tema y puede que lo explicado no les afecte a todos. Hable con su médico de familia para averiguar si esta información es útil para usted y para aprender más acerca del tema.

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Medicine and Your Child:

How to give the right dose

What do I need to know about my child's over-the-counter (OTC) medicines?

Both your doctor and your pharmacist can answer your questions about OTC medicines. Here are some useful things to know about medicines that are to be taken by mouth (oral medicines):

- The name of the medicine
- What the medicine is for
- The dose (amount) of the medicine to give
- The number of times a day the medicine should be given
- Whether the medicine can be given with food
- The number of days the medicine should be given
- How you will know the medicine is working
- The most common and important side effects

What should I tell the doctor?

At the time you ask your doctor about an OTC medicine or he or she suggests that you give your child one, you should be sure to tell your doctor these things:

- Other medicines that your child is taking (both prescription and OTC medicines)
- Any drug allergies your child has
- If the medicine costs too much for you to buy

Things to remember about giving medicine to your child

When your doctor says to give the medicine “every 6 hours,” that generally means the medicine is taken 4 times a day (for example, at breakfast, lunch, supper and bedtime). It doesn’t generally mean to wake

the child up in the night to take medicine. And “take every 8 hours” generally means the medicine should be taken 3 times a day.

Pay close attention to the dosage given on the label. Labels for liquid medicines give measurements in both teaspoons (tsp) and in milliliters (mL). Your pharmacist can give you a measuring device—a spoon that’s made especially for measuring medicine, a syringe or a cup—that’s labeled with both tsp and mL. Your pharmacist should also show you how to use it. One tsp is not the same as 1 mL—read the label carefully and make sure you give the right amount of medicine to your child. An ordinary kitchen teaspoon may not hold the right amount of medicine.

Measure the medicine carefully. If you’re using a measuring cup, set it on a level surface such as a countertop and then pour the medicine in it.

Sometimes people think, “If a little medicine is good, a lot is better (or will work quicker).” This is wrong. Giving too much medicine can be harmful. Be sure you only give the recommended dose of each medicine.

If you use a syringe-type measuring device to give liquid medicine to your child, first throw away the small cap of the syringe. Children can choke on these caps.

If your child has a bad reaction to a medicine or is allergic to a medicine, tell your doctor right away. Also, keep a record of the following information at home: the name of the medicine, the dosage directions, the illness the medicine was used for and the side effects the medicine caused.



American Academy
of Family Physicians

TODAY'S FAMILY PHYSICIAN - SPECIALIZING IN ALL OF YOU

This handout provides a general overview on this topic and may not apply to everyone. To find out if this handout applies to you and to get more information on this subject, talk to your family doctor.

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Medicamentos y su Hijo/a: Como darle la dosis correcta

¿Qué es lo que necesito saber acerca de los medicamentos sin receta médica (SRM) de mi hijo/a?

Ambos, el médico de su hijo/a y el farmacéutico le darán información acerca de los medicamentos que ha comprado sin receta (SRM). Aquí le damos unos consejos que debe saber acerca de los medicamentos orales (que se toman por la boca):

- El nombre de la medicamento
- Para qué es el medicamento
- La dosis del medicamento que necesita administrar
- El número de veces que necesita tomar el medicamento al día
- Las horas del día que necesita administrar el medicamento
- Si puede tomar el medicamento con comida
- El número de días que necesita tomar el medicamento
- Cómo sabrá que el medicamento está funcionando
- Los más comunes e importantes efectos secundarios

¿Qué le debo decir al doctor?

A la hora que le pregunta al doctor sobre un medicamento sin receta médica (SRM)

o él/ella sugiere que debe darlo uno a sus niño/a, usted debe estar seguro de decirle al doctor lo siguiente:

- Si el niño/a está tomando otros medicamentos (con o sin receta médica)
- Cualquier alergia a medicamentos que su hijo/a tenga
- Si los medicamentos van a ser demasiado caros para que usted los compre

¿Qué es lo que puedo esperar del farmacéutico?

El farmacéutico le debe decir las mismas cosas que su médico le dijo acerca del medicamento. Para medicamentos líquidos, el farmacéutico le dará un aparato medidor y le enseñará la manera correcta de usarlo. El farmacéutico le responderá cualquier pregunta que tenga acerca del medicamento.

Cosas que necesita acordarse cuando le dé medicamentos a su hijo/a

- Cuando el médico dice dar el medicamento “cada 6 horas” en una receta, esto generalmente quiere decir que el medicamento se debe tomar 4 veces al día (por ejemplo, en el desayuno, el almuerzo, la cena y la hora de acostarse). Generalmente no quiere decir que tiene que



despertar a su hijo/a en medio de la noche para darle el medicamento. Y “cada 8 horas” generalmente quiere decir que se debe tomar 3 veces al día.

- Ponga atención cuidadosa a la dosis indicada en la etiqueta. Las etiquetas dan las medidas en ambos cucharaditas (tsp) y mililitros (mL). Use un aparato medidor—una cucharadita hecha especialmente para medir medicamentos, una jeringa o una taza etiquetada en cucharaditas y mililitros. Una cucharadita no es igual a un mililitro—lea vd. cuidadosamente la etiqueta y asegúrese de darle la cantidad apropiada del medicamento a su niño/a.
- Mide el medicamento cuidadosamente. Si usa una taza medidora, póngala en una superficie nivel como por ejemplo una encimera y entonces verter el medicamento medicina en la taza.
- A veces las personas piensan que “Si un poco de medicamento ayuda, entonces más medicamento ayuda más (o trabajará más rápido)”, pero esto no es cierto. Darle demasiado medicamento a su hijo/a puede ser muy dañino. Asegúrese de darle sólo la cantidad recomendada de cada medicamento.
- Aunque su hijo se sienta mejor, continúe dándole el medicamento como el doctor ha recomendado.
- Use un aparato medidor de medicamento con las que son líquidas para dar la dosis correcta. Una cuchara ordinaria de cocina puede que no tenga la cantidad correcta de medicamento.
- Si usa una jeringa como un aparato medidor, para administrar medicamento líquido, primero bote la tapa de jebes de la jeringa. Los niños se pueden atorar con estas tapas.
- Si su hijo tiene una mala reacción al medicamento o es alérgico al medicamento, dígame a su doctor de inmediato. Esta información es muy importante para los médicos. Usted también tiene que mantener notas acerca de estos medicamentos en su casa, el nombre del medicamento, la dosis, para qué fueron recetadas y los efectos secundarios que el medicamento causó.
- Si usted o su hijo/a tiene algún problema con la receta médica, hable con su médico o farmacéutico inmediatamente.

Este panfleto provee un resumen del tema y puede que lo explicado no les afecte a todos. Hable con su médico de familia para averiguar si esta información es útil para usted y para aprender más acerca del tema.

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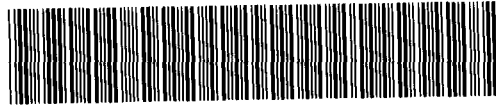
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