



# Health Management Bulletin

## OTC ANALGESICS

### Education Modules for Physicians

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## Over-the-Counter Analgesics in Adult Patients—An Overview

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**T**here are a number of medical conditions for which physicians may recommend an over-the-counter (OTC) analgesic; in some cases, an OTC product may be a suitable alternative to a prescription drug, such as in osteoarthritis, soft tissue injuries, colds and flu, headaches, dysmenorrhea, and other painful conditions. Thus, physicians should be aware of the wide variety of OTC analgesics readily available for purchase by their patients.

One only has to look at the rows of OTC analgesics lining pharmacy and supermarket shelves to get a sense of the market for these products. It is estimated that Americans spend over \$2 billion every year for OTC analgesics. The number of products is also growing, with the introduction of new OTC nonsteroidal anti-inflammatory drugs (NSAIDs) and combination products. For physicians, the abundance of OTC analgesics suggests the following:

- Since patients may seek advice regarding the optimal OTC product for a specific complaint, physicians should be knowledgeable about the available OTC products.
- As part of the patient history, physicians should inquire about OTC drug use, especially for patients with chronic pain conditions.
- Patients must be reminded never to exceed the recommended dosages of an OTC analgesic without consulting a physician; patients may assume that OTC drugs are harmless, no matter what the dosage. Overuse of some OTC products can exacerbate some conditions. For example, in patients with headaches, overuse of OTC analgesic preparations (particularly those containing caffeine) can lead to rebound headaches, creating a vicious cycle of drug use begetting further drug use. Patients may also

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inadvertently exceed recommended dosages by combining products. For example, patients may simultaneously take a cold and flu product (containing acetaminophen, aspirin or ibuprofen) with a headache product that contains the same analgesic.

- Patients should be encouraged to ask their physician or other health care professional for advice regarding OTC products.
- When patients seek physician treatment for painful conditions, they may be expecting a prescription drug. Physicians may want to consider whether an OTC product is a suitable treatment option.

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This Health Management Bulletin is the fourth in a series on OTC Analgesics; it summarizes information on currently available OTC analgesics and discusses their appropriate use for headache, muscle and joint pain, and gynecologic conditions. The special concerns relating to OTC analgesic use by older patients are addressed in separate Health Management Bulletins.

#### ■ **Overview of OTC Analgesics**

Considering the abundance of products on pharmacy or supermarket shelves, it is remarkable that the OTC analgesic options derive from five basic drugs: acetaminophen, aspirin, ibuprofen, ketoprofen, and naproxen sodium. Ibuprofen (eg, Advil, Motrin IB, Nuprin), ketoprofen (eg, Orudis KT, Actron), and naproxen sodium (Aleve) are OTC NSAIDs in the same subfamily of propionic acid derivatives. A variety of generic or brand name products, combination products, different dosages or preparations (eg, liquids, tablets, gelcaps, etc.) all contribute to the wealth of options available to the patient.

#### ■ **Mechanism of Action**

NSAIDs (including aspirin) act primarily by inhibiting the synthesis of prostaglandins from arachidonic acid. This anti-prostaglandin effect is thought to be the major mechanism of action of NSAIDs; it may produce analgesia by blocking prostaglandin-related pain impulse generation, or through inhibition of other pain mediators, such as bradykinin or histamine. Higher doses (typically prescription level) of NSAIDs also produce anti-inflammatory effects. Although the precise mechanisms of the anti-inflammatory effects of NSAIDs are uncertain, it is thought to be related, in part, to prostaglandin inhibition. Prostaglandins are released from injured cells and cause erythema, vasodilation and hyperalgesia. Other anti-inflammatory effects of NSAIDs are inhibition of leukocyte migration, inhibition of lysozymal enzymes, or interference with other cell processes, such as cell binding or transmembrane ion fluxes. An NSAID dose higher than that required to inhibit prostaglandin synthesis may be required for an optimal anti-inflammatory effect, suggesting that the anti-inflammatory effect of NSAIDs are not wholly due to their anti-prostaglandin effect.

The mechanism of action of acetaminophen is not fully known, but may be related to prostaglandin inhibition in the central nervous system, or the blocking of peripheral pain transmission. Acetaminophen has only very minimal anti-inflammatory effects. Although the lack of anti-inflammatory action is one of the major clinical differences between acetaminophen and NSAIDs, it is important to note that at the doses recommended for OTC use, NSAIDs do not have maximum anti-inflammatory action.<sup>1,2</sup>

Aspirin, acetaminophen and NSAIDs all have therapeutically useful antipyretic activity, thought to be related to inhibition of prostaglandin synthesis in the hypothalamus.

#### ■ **OTC Analgesic Dosage Forms**

Physicians should be familiar with available OTC analgesics, dosage forms, and recommended analgesic doses. When discussing OTC analgesic use with patients, they should be assured that generic brands of aspirin, acetaminophen or ibuprofen are equivalent to brand name products, and are usually less expensive. Table 1 provides an overview of the dosage forms and analgesic dosages for the currently available OTC analgesics.

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**Table 1. OTC Analgesics, Dosage Forms, and Adult Dosage**

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<b>OTC Analgesic</b>	<b>Dosage Forms</b>	<b>Adult Analgesic Dosage</b>
<b><i>Acetaminophen</i></b>	<ul style="list-style-type: none"><li>• 325 mg Tablets, Caplets</li><li>• 500 mg Tablets, Caplets, Gelcaps, Geltabs, Liquid</li><li>• 650 mg Extended Relief Caplets</li></ul>	<ul style="list-style-type: none"><li>• Two tablets/caplets every 4-6 h; maximum 12/day or 4000mg/day</li><li>• Two tablets/caplets/gelcaps/geltabs or 2 TB liquid every 4-6 h; maximum 8/day</li><li>• Two tablets/caplets every 8 h; not to exceed 6/day</li></ul>
<b><i>Aspirin</i></b>	<ul style="list-style-type: none"><li>• 325 mg Tablets (including enteric and buffered preparations)</li><li>• 500 mg Tablets (including enteric and buffered preparations)</li><li>• 650 mg Tablets (including enteric and timed-release preparations)</li></ul>	<ul style="list-style-type: none"><li>• One to two tablets every 4 h; maximum 12 tablets/day</li><li>• One to two tablets every 3 h, or two tablets every 6 h; maximum 8 tablets/day or 4,000 mg/day</li><li>• One to two tablets every 8 h; maximum 6/day</li></ul>
<b><i>Ibuprofen</i></b>	<ul style="list-style-type: none"><li>• 200 mg Tablets, Caplets, Gelcaps, Liquid gel</li></ul>	<ul style="list-style-type: none"><li>• One to two tablets/caplets/gelcaps every 4-6 h; maximum 6/day or 1,200 mg/day</li></ul>
<b><i>Ketoprofen</i></b>	<ul style="list-style-type: none"><li>• 12.5 mg Tablets</li></ul>	<ul style="list-style-type: none"><li>• One to two tablets every 6-8 h; maximum 6/day or 75 mg/day</li></ul>
<b><i>Naproxen sodium</i></b>	<ul style="list-style-type: none"><li>• 220 mg Tablets, Caplets</li></ul>	<ul style="list-style-type: none"><li>• One tablet/caplet every 8-12 h; maximum 3/day or 660 mg/day</li></ul>

Dosages of ibuprofen greater than 400 mg do not have increased analgesic efficacy, but the higher dosage will have anti-inflammatory activity.

Comparisons of the analgesic efficacy of acetaminophen and NSAIDs suggest that at the recommended doses, the two are equivalent. Using the treatment of osteoarthritis as an example, in a double-blind trial which randomized 184 patients with mild-to-moderate osteoarthritis of the knee to receive either 2400 mg or 1200 mg of ibuprofen daily, or 4000 mg of acetaminophen daily (the 2400 mg dosage of ibuprofen is considered anti-inflammatory, while the 1200 mg dosage is analgesic), it was concluded that acetaminophen was as

effective as either dose of ibuprofen.<sup>3</sup> However, in the treatment of the pain and discomfort of dysmenorrhea, ibuprofen is considered more effective than other OTC analgesics.

Comparisons of efficacy among the various NSAID products have shown that across populations, no one NSAID product is clearly superior to another. However, there is great vari-

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ability in individual patient response. Thus, if one NSAID preparation does not bring relief, the patient may experience benefit with a different OTC NSAID; the choice is an empiric one and it should be made with patient characteristics in mind. For example, naproxen sodium is a long-acting NSAID and for that reason, the maximum daily dosage is lower than other NSAID products; for elderly patients, it is recommended that it be taken only twice daily. Although long-acting drugs have convenient dosing schedules with fewer doses needed through-out the day, these preparations are typically associated with a slow onset of action. Therefore, naproxen sodium may not be suitable for patients who need quick pain relief, such as patients with migraines.

### ■ Combination Products

The analgesics aspirin, acetaminophen or ibuprofen have been combined with antihistamines, cough suppressants or nasal decongestants in OTC cold and flu medicines. Products containing antihistamines, such as diphenhydramine or chlorpheniramine, are often marketed as nighttime preparations, because of their associated side effect of drowsiness. Both aspirin and acetaminophen may be combined with caffeine, which is thought to act as an analgesic adjuvant with aspirin. The combination of aspirin, acetaminophen and caffeine has been shown to be an effective OTC treatment for migraines and tension-type headaches. One recent study reported on three randomized placebo-controlled trials that examined the efficacy of the combination of acetaminophen, aspirin and caffeine for migraines.<sup>4</sup> All three trials excluded patients with severely disabling migraines, (ie, migraines that required

bedrest or were associated with vomiting in at least 20% of attacks). The combination therapy was significantly superior to placebo, with pain intensity reduced to mild or none in 59% of patients. However, heavy coffee drinkers may want to avoid these compounds, as caffeine can aggravate headaches.

### ■ Brand Confusion

Many familiar brand names of drugs represent families of products and not just individual drugs. Patients taking a combination cold preparation, and a separate analgesic for associated headaches, may not realize that by taking both preparations, they are most likely exceeding the recommended dosage for the analgesic drug.

### ■ Side Effects of OTC Drugs

#### ***Acetaminophen***

Acetaminophen is generally considered a well-tolerated drug that is nontoxic in therapeutic doses. Acute side effects include sensitivity reactions such as rash and urticaria; anaphylactoid reactions occur rarely. Leukopenia and pancytopenia have been reported rarely with prolonged high doses. Although chronic ingestion of large doses of acetaminophen and other analgesics has been reported to be associated with the development of analgesic nephropathy, characterized by papillary necrosis and interstitial nephritis, this occurrence is rare. This risk may be increased among those with previous renal damage. An overdose of acetaminophen can lead to hepatic necrosis, particularly in conjunction with chronic alcoholism. Therefore, patients with a history of alcohol dependency should consult their physician before using acetaminophen, and patients should be questioned about their ingestion of alcohol if they regularly take acetaminophen. Drug interactions with acetaminophen include anticonvulsants that increase hepatic microsomal enzyme action, and may increase the potential for liver toxicity, although this risk is minimal with therapeutic dosages of acetaminophen in healthy individuals. Barbiturates, rifampin and sulfinpyrazone may also increase hepatic microsomal enzyme activity, potentially increasing the risk of liver toxicity. Prolonged use of acetaminophen may also potentiate the effects of anticoagulants.<sup>1,5,6</sup>

#### ***NSAIDs***

The side effects of NSAIDs, particularly gastrointestinal, have been widely documented. For example, in one study, 30% of elderly patients with acute hospital admission for gastrointestinal problems were receiving NSAIDs and in 20%, NSAIDs were considered the likely cause of hospital admission.<sup>7</sup> One-third of patients reported no beneficial effects from the NSAIDs and they were withdrawn successfully in 75% of patients. Based on FDA estimates, approximately 3% of NSAID users develop serious NSAID-induced gastrointestinal complications each year, resulting in 200,000 cases of bleeding or perforated ulcers, and at least 10,000 deaths annually.<sup>8</sup> This serious side effect should not be confused with the 20% to 30% incidence of dyspepsia (primarily in the elderly and those individuals with sensitive stomachs).

Dyspepsia from NSAIDs is a local effect that does not correlate with the risk of developing true gastropathy (ie, GI ulcers). Ulcers result from systemically circulating NSAIDs,

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which back diffuse into the gastric mucosa from the blood. Elderly patients are considered at a higher risk of suffering GI complications. For example, a meta-analysis of 16 studies of NSAID use reported that patients older than 60 years had a three-fold higher relative risk (5.52) of GI complications than those younger than 60 (1.65).<sup>9</sup> FDA labeling for NSAIDs recommends that patients consuming three or more alcoholic drinks per day should consult with their physician before using NSAIDs; alcohol alone increases the risk of GI bleeding, and can have an additive effect in patients taking NSAIDs.

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In addition to the common GI side effects, NSAIDs are associated with renal toxicity, related to the antiprostaglandin effects of NSAIDs. Prostaglandins are produced in the renal medulla and regulate renal salt and water excretion, glomerular filtration rate, vascular resistance and renin secretion. While the kidneys of normal, healthy patients produce an adequate amount of prostaglandin, NSAIDs can seriously impair the production of prostaglandins in those with preexisting renal disease. Therefore, older patients with preexisting intrinsic or extrinsic renal impairment (including congestive heart failure, cirrhosis, volume or water depletion) are at high-risk for renal toxicities. The most common manifestation is a rise in serum creatinine level. Acute renal insufficiency may also occur, characterized by an increase in BUN, body weight, creatinine and serum potassium. This acute renal insufficiency typically resolves promptly with discontinuation of the drug. Other renal toxicities may occur, including peripheral edema, interstitial nephritis, and papillary necrosis. Interstitial nephritis typically presents as the nephrotic syndrome, but dialysis may be required acutely.<sup>2</sup>

Chronic renal disease caused by interstitial nephritis has been reported with NSAID use. NSAID use was investigated in a case control study of 554 patients who were discharged from the hospital with a diagnosis of chronic renal dysfunction. There was a two-fold increased risk of chronic renal disease among NSAID users.<sup>10</sup> In a subgroup analysis, the risk was increased ten-fold in men over the age of 65, presumably because of co-existing, age-related vascular changes. It should also be noted that in individuals with considerable dehydration, it is advisable to rehydrate patients first, before initiating NSAID therapy.

Given the large number of patients taking NSAIDs, NSAID-related morbidity is commonly reported. However, appropriate use of NSAIDs, even on a chronic basis, does not inevitably result in morbidity. Many thousands of patients have safely taken routine doses of NSAIDs over a period of years.

### ***Aspirin***

The side effects of aspirin are similar to those of other NSAIDs. The gastrointestinal side effects of aspirin are well-known. There has been some debate over the potential of buffered aspirin to reduce gastric irritation. Well-designed studies have shown that buffered aspirin does not cause less gastric irritation than regular aspirin.<sup>5</sup> Enteric-coated aspirin tablets may reduce stomach irritation by delaying absorption; however, delayed absorption will result in a delayed onset of action. The antiplatelet effect of aspirin can be either an asset or a liability. Low-dose aspirin is now recommended for patients with a previous myocardial infarction, or unstable angina, as a therapeutic agent to reduce the risk of vascular mortality and/or nonfatal reinfarction. In contrast, aspirin is generally contraindicated 5-7 days prior to surgery. Allergic reactions to aspirin are relatively uncommon, occurring in about 0.3% of the general population. The incidence of allergic reactions is highest in persons with chronic urticaria (20%), asthma (4%), and chronic rhinitis (1.5%). The association of aspirin sensitivity, asthma, and nasal polyps is referred to as the “aspirin triad.” Interestingly, the nasal symptoms may occur first, followed by asthma, and finally by aspirin sensitivity. Allergic reactions to aspirin are thought to be related to the inhibition of prostaglandin synthesis; therefore, any patient with an allergic reaction to aspirin should avoid taking other NSAIDs, which also inhibit prostaglandin synthesis.

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Of particular importance in children is the association of aspirin with Reye's syndrome—a rare, but potentially fatal disease. The risk of Reye's syndrome is highest in children or teenagers with symptoms suggestive of chicken pox or flu. Since these symptoms include cough, sore throat or fever, many physicians no longer recommend aspirin use in children.

■ **Specific Indications for OTC Analgesics**

***Osteoarthritis***

Guidelines for the treatment of osteoarthritis of the hip and knee have been published by the American College of

Rheumatology (ACR).<sup>11,12</sup> The management of osteoarthritis requires a multifaceted approach, which includes patient education, physical therapy, various techniques of joint protection, lifestyle modifications and drug therapy. Although the keystone of therapy is nonpharmacologic, drug therapy is an important adjunct to reducing pain and preventing disability. Drug therapy focuses on the use of simple analgesics, such as acetaminophen or NSAIDs, used primarily for their analgesic and potentially, for their antiinflammatory effects. The ACR guidelines recommend, in addition to nonpharmacologic modalities, acetaminophen at doses up to 1 g qid as the initial drug of choice for systemic treatment of symptomatic osteoarthritis of the hip and knee; if response to acetaminophen is suboptimal, low-dose NSAIDs, followed by anti-inflammatory doses of NSAIDs, can be used.

The recommendation of acetaminophen as the first-line drug therapy reflects the equal analgesic efficacy of acetaminophen and the NSAIDs, the uncertain contribution of inflammation to the pathology of osteoarthritis, and the increased risk of NSAID-related morbidity, particularly in an older patient population.

***Soft Tissue Injuries***

Soft tissue injuries—most commonly, muscle strains or sprains—typically include an element of inflammation. Although acetaminophen is an effective analgesic for most mild-to-moderate pain, aspirin or NSAIDs may be preferred due to their anti-inflammatory action (although this is minimal at recommended OTC dosages). For example, a typical analgesic dose of ibuprofen is 200–400 mg every 4 to 6 hours (up to 1,200 mg/day), while an anti-inflammatory dose of ibuprofen may range up to a 3200 mg daily dose. In 1998, the American Geriatrics Society published clinical guidelines on the management of chronic pain in the older population. While these guidelines did not focus on specific etiologies of pain, they recommend acetaminophen as the drug of choice for relieving mild-to-moderate musculoskeletal pain.<sup>13</sup>

***Colds and Flu***

Treatment of colds and influenza is a significant component of the primary care physician's office practice. Treatment can only be described as palliative, with a variety of single and combination OTC preparations designed to ease the most common symptoms of colds and flu (ie, congestion, rhinorrhea, coryza, cough, myalgias and fever). Acetaminophen, aspirin (except in children), and other NSAIDs are commonly recommended to relieve the fever, headaches, and myalgias associated with colds and flu. Acetaminophen is recommended by the American Lung Association for the treatment of the symptoms of colds and flu.<sup>14</sup>

***Headaches, including Migraine***

For the occasional headache, any OTC analgesic may provide adequate pain relief, and these may also be effective treatment for migraine headaches. One basic principle of migraine pharmacotherapy is that an adequate dose should be taken as soon as possible after the onset of symptoms. For more severe headaches or migraine headaches, the combination of aspirin, acetaminophen and caffeine has been found to be effective.<sup>4</sup> Patients should be cautioned about rebound headaches, which can progress to chronic headaches, with long-term frequent use of OTC analgesics.

## Dysmenorrhea

NSAIDs are considered the treatment of choice for dysmenorrhea. Primary dysmenorrhea is related to the release of excess endometrial prostaglandin during menstruation, which in turn precipitates uterine contractions. NSAID therapy is generally so successful, that some suggest the diagnosis should be questioned in non-responders.<sup>15</sup> Secondary dysmenorrhea is related to a variety of pathologies (eg, endometriosis, adenomyosis) that also respond to NSAID therapy, although specific treatment for the underlying disorder may be required in more severe cases.

The peripheral antiprostaglandin action of NSAIDs is responsible for their success in treating dysmenorrhea. While patients with mild-to-moderate primary dysmenorrhea may respond to OTC recommended doses, severely symptomatic patients may require higher doses.

### ■ Summary

**Over-the-counter analgesics have a valuable role in treating everyday pain symptoms, and they are likely found in almost every household medicine cabinet. Because of their ubiquity, it is important for physicians to understand the strengths, limitations and pitfalls of patient self-medication with either acetaminophen or NSAIDs, including aspirin. While any OTC analgesic may be effective for the occasional ache or pain, long-term administration of OTC analgesics for chronic conditions must be carefully reviewed by the physician, both to ensure that patients are not exceeding the recommended dosages, and secondly, to assess long-term morbidities—particularly the risk of NSAID-induced gastropathy. Additional pitfalls include the confusion patients face when trying to select an OTC analgesic from the myriad of products available. Physicians may remind patients that OTC analgesics can be broken down into two basic categories—acetaminophen and NSAIDs (including aspirin). Physicians can help to educate their patients on the use of OTC analgesics by determining any special risks, explaining how to avoid drug interactions, and advising their patients to read the labels carefully and adhere to the recommended dosages and duration of use. Physicians should always inquire about alcohol use before recommending an OTC analgesic. These products can offer significant advantages when used correctly, and patient education is the key to the responsible use of any OTC analgesic. Therefore, it is also important that patients be directed to consult their physicians periodically to reevaluate their need for these medications.**

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This Health Management Bulletin is the fourth in a series of education modules on OTC Analgesics. Other topics include ***Aspirin and Cardiovascular Disease*** (with complimentary patient education materials, ***Reducing Your Risk of Heart Attack and Stroke—The Role of Aspirin***), ***OTC Analgesia in Older Persons***, and ***OTC Analgesia in Colds and Influenza***. If you would like to receive copies of any or all of these publications, please write to the AMA at the address to the right.

#### OTC ANALGESICS IN ADULT PATIENTS—AN OVERVIEW

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