

# Is it time to reconsider the approach to dental pain relief?

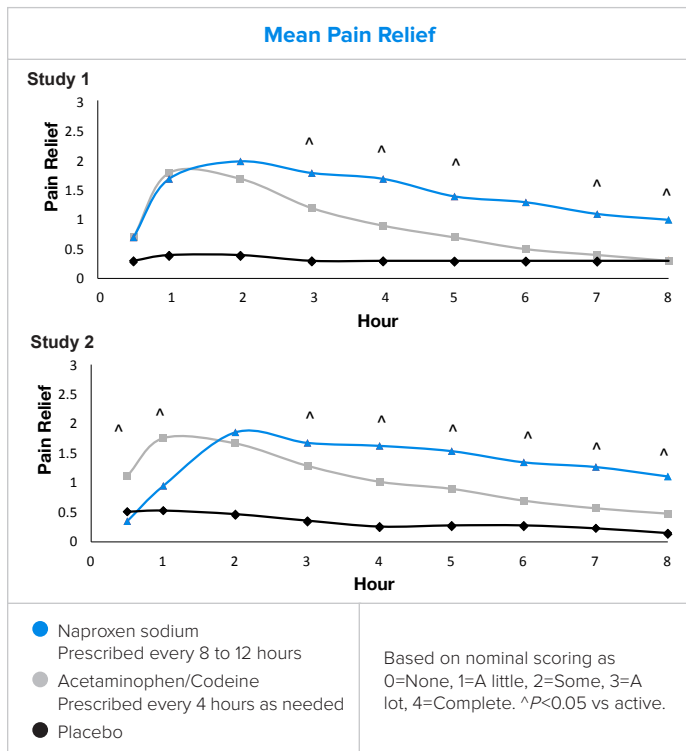
## A clinically proven nonprescription option for dental pain relief

Pain relief is a serious concern for dentists. Dental pain has been proven responsive to Aleve®, a nonsteroidal anti-inflammatory drug (NSAID), at nonprescription strength.<sup>1-3</sup> Aleve® is an over-the-counter (OTC) pain reliever indicated for temporary relief of minor aches and pains including minor arthritis pain, headache, muscular aches and toothache.<sup>4</sup>

### In two clinical studies

## Proven efficacy of Aleve®: strength and duration vs acetaminophen plus codeine

Two 8-hour studies (N=455) compared 1 dose of Aleve® 440 mg with 1 dose of acetaminophen 600 mg/codeine 60 mg after surgical removal of 3 or 4 molars (≥1 impacted). From the 3-hour mark onward in both studies, patients who took Aleve® reported significantly reduced pain compared with those taking acetaminophen plus codeine ( $P<0.05$ ).<sup>5</sup> The 12-hour strength of Aleve® also gave patients more sustained pain relief per dose, as demonstrated by a longer median time to remedication, versus patients on acetaminophen plus codeine ( $P<0.05$ ), which is commonly prescribed every 4 hours as needed.<sup>5,6</sup>

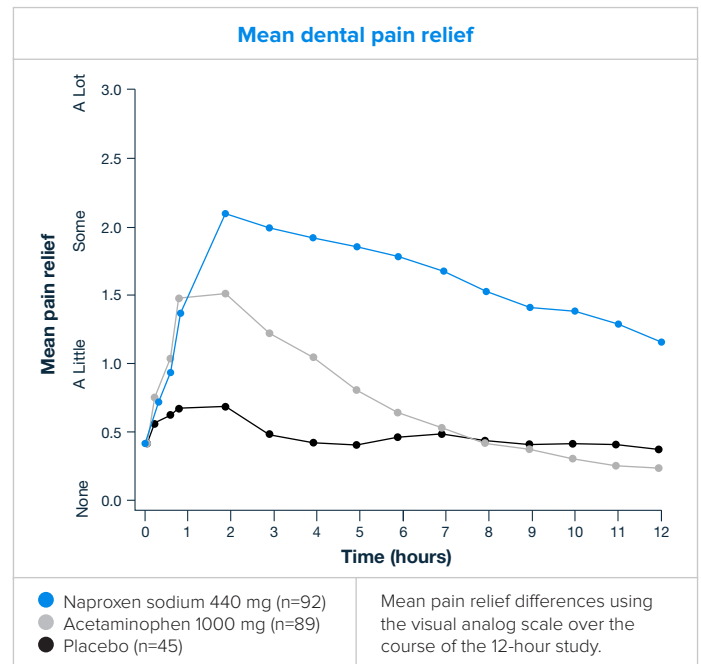


### In a clinical study

## Proven efficacy of Aleve®: strength and duration vs acetaminophen

A controlled single dose clinical trial compared efficacy and duration of action of 440 mg Aleve® (n=92), 1000 mg acetaminophen (n=89), and placebo (n=45) in a single-dose, randomized, double-blind, 12-hour study of patients with at least moderate pain after extraction of 3 or 4 third molars.<sup>1</sup> The study demonstrated that mean pain relief with Aleve® was significantly superior to both placebo and acetaminophen at hours 4 through 12 after initial dosing ( $P<0.05$ ).<sup>1</sup>

In the trial, patients taking acetaminophen required remedication as soon as 3 hours later, and there was no significant difference in pain relief between acetaminophen and placebo at 6 hours.<sup>1</sup>

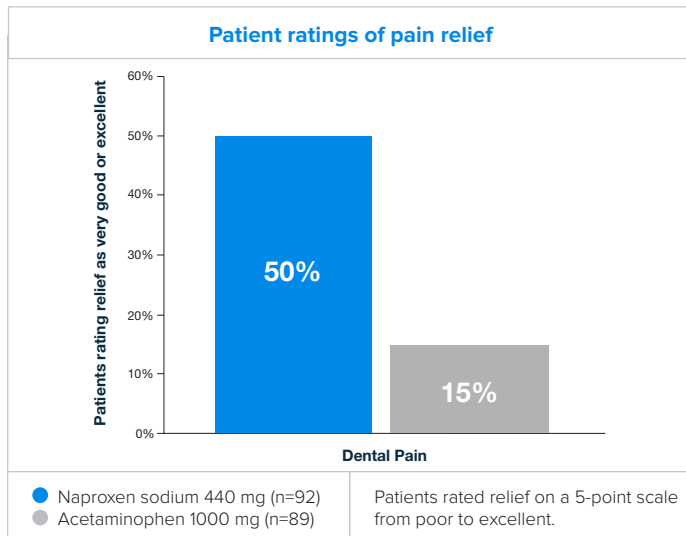


The same clinical trial demonstrated that the median time to onset of action for Aleve® after dental extraction was similar to acetaminophen.<sup>1</sup>



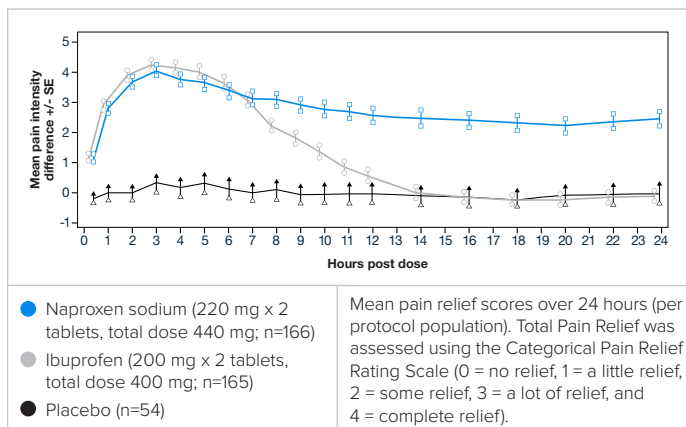
**In a clinical study  
Higher patient ratings of pain relief seen with  
Aleve® than with acetaminophen**

In a trial in dental pain, 3 times more patients reported the overall effectiveness of Aleve® as very good or excellent versus acetaminophen. A greater percentage of patients rated acetaminophen as good or fair versus Aleve®.<sup>5</sup>



**In a clinical study  
Proven duration of Aleve® vs ibuprofen**

A single-center, randomized, double-blind, placebo-controlled study demonstrated that the duration of pain relief after a single dose of Aleve® 440 mg was significantly longer than ibuprofen 400 mg in post-surgical dental pain. Significantly fewer Aleve®-treated subjects required rescue medication over a 24-hour period.<sup>7</sup>



**Professional guidelines recommend NSAIDs as first-line minor pain treatment**

In response to the increase in prescription opioid abuse, dental associations now recommend NSAIDs like Aleve® over opioids.<sup>2,3</sup> The American Dental Association recommends NSAIDs like naproxen as first-line therapy for acute pain management,<sup>2</sup> and the American Association of Oral and Maxillofacial Surgeons recommends NSAIDs like naproxen as a first-line analgesic therapy for the management of acute and postoperative pain.<sup>3</sup> Aleve® is indicated for the temporary relief of minor aches and pains.

**Summary**

Aleve® is an OTC pain reliever with proven efficacy, duration, and a similar median time to onset of action as acetaminophen in dental pain. It is safe when used as directed,<sup>8</sup> and multiple professional societies recommend NSAIDs to treat minor dental pain. With billions of courses of treatment, Aleve® continues to help patients carry on with their daily activities.<sup>9</sup>

**References:** 1. Kiersch TA, Halladay SC, Hormel PC. A single-dose, double-blind comparison of naproxen sodium, acetaminophen, and placebo in postoperative dental pain. *Clin Ther.* 1994;16(3):394-404. 2. American Dental Association announces new policy to combat opioid epidemic. News release. American Dental Association. March 26, 2018. Accessed April 16, 2020. <https://www.ada.org/en/press-room/news-releases/2018-archives/march/american-dental-association-announces-new-policy-to-combat-opioid-epidemic>. 3. American Association of Oral and Maxillofacial Surgeons. Opioid prescribing: acute and postoperative pain management. Accessed April 16, 2020. [https://www.aaoms.org/docs/govt\\_affairs/advocacy\\_white\\_papers/opioid\\_prescribing.pdf](https://www.aaoms.org/docs/govt_affairs/advocacy_white_papers/opioid_prescribing.pdf). 4. ALEVE Caplets. Drug facts. Bayer HealthCare; April 2018. 5. Data on file, Bayer Consumer Health. 6. TYLENOL® with codeine prescribing information. Janssen Pharmaceuticals, Inc.; October 2019. 7. Cooper SA, Desjardins P, Brain P, et al. Longer analgesic effect with naproxen sodium than ibuprofen in post-surgical dental pain: a randomized, double-blind, placebo-controlled, single-dose trial. *Curr Med Res Opin.* 2019;35(12):2149-2158. 8. Bansal V, Dex T, Proskin H, Garreffa S. A look at the safety profile of over-the-counter naproxen sodium: a meta-analysis. *J Clin Pharmacol.* 2001;41:127-138. 9. DeArmond B, Francisco CA, Lin J-S, et al. Safety profile of over-the-counter naproxen sodium. *Clin Ther.* 1995;17(4):587-601.

SEM=Standard Error of the Mean.



Aleve, Bayer and the Bayer Cross are registered trademarks of Bayer. All rights reserved unless otherwise indicated. All trademarks are owned by Bayer and its affiliates or licensed for its use. © 2020 Bayer May 2020 PP-AL-P-US-1123

