

# In a new, single-dose study, Aleve® was proven as strong\* as HYD+APAP for dental pain<sup>1</sup>

\*In hours 0 to 4 of a single-dose dental study of Aleve® (440 mg), HYD+APAP (10 mg + 650 mg), or placebo.

Aleve® is an OTC pain reliever indicated for temporary relief of minor aches and pains including arthritis pain, headache, muscular aches, and toothache.<sup>2</sup>

## Learn how non-addictive OTC NSAIDs like Aleve® can help you reduce risk factors that contribute to the US opioid crisis<sup>1,3,4</sup>

Did you know that up to half of opioid prescriptions at dental visits are inconsistent with the guidelines on appropriate use of opioids?<sup>4</sup> In response to the overuse of opioids, there is an increasing interest in the effectiveness of OTC NSAIDs in alleviating pain—to reduce the need for opioids. Growing evidence supports Aleve® as a powerful\* non-opioid OTC treatment for minor dental pain.<sup>1,2,5,6</sup>

In the study, Aleve® was as effective\* for dental pain, lasted longer, and was better tolerated vs a widely prescribed opioid combination, HYD+APAP<sup>1</sup>

## In a recent single-center, randomized, double-blind, parallel, placebo-controlled study, Aleve®, a non-opioid OTC NSAID, was compared with hydrocodone plus acetaminophen (HYD+APAP) for dental pain relief<sup>1</sup>

- Patients experiencing moderate or severe pain (N=221) after surgical removal of impacted third molars were randomized to receive either a single dose of Aleve® (440 mg [n=90]), HYD+APAP (10 mg + 650 mg [n=87]), or placebo (n=44)<sup>1</sup>
- The primary objective was to compare Sum of Pain Intensity Difference from 0 to 12 hours (SPID<sub>0-12</sub>) after a single oral dose
  - Secondary objectives were to compare the total pain relief (TOTPAR) over 6 and 12 hours (SPID<sub>0-6</sub>), time to onset of pain relief, time to first use of rescue medication, and duration of pain intensity at least half gone over 6 and 12 hours<sup>1</sup>
  - SPID<sub>0-4</sub> was also assessed

Aleve® was as effective as HYD+APAP in hours 0 to 4 at reducing pain intensity (based on SPID from 0 to 4 hours, or SPID<sub>0-4</sub>).<sup>1</sup>

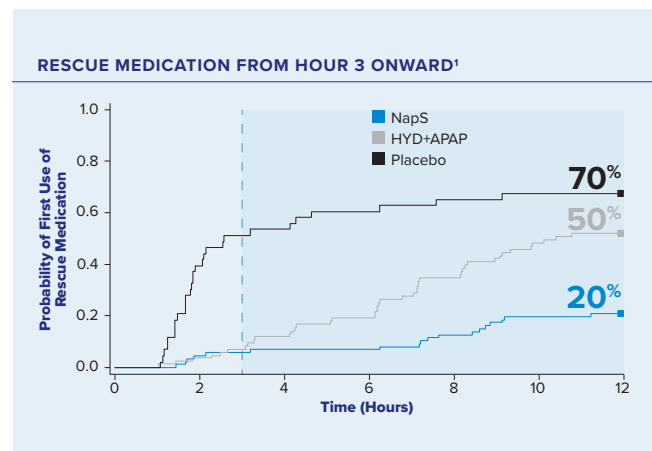
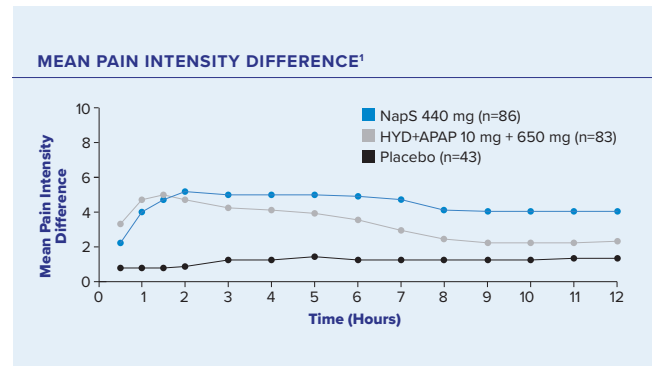
### The primary endpoint was met<sup>1</sup>

- SPID<sub>0-12</sub> was statistically significant for Aleve® vs HYD+APAP<sup>1</sup>

## Key secondary endpoints also showed statistical significance in favor of Aleve® compared with HYD+APAP<sup>1</sup>:

- Total pain relief (0 to 6 and 0 to 12 hours;  $P < 0.05$ )<sup>1</sup>
- Median time to rescue medication ( $P < 0.001$ )<sup>1</sup>
- Duration of pain at least half gone over 12 hours ( $P < 0.001$ )<sup>1</sup>

Both active treatments were significantly more effective than placebo.<sup>1</sup> HYD+APAP was not statistically superior to Aleve® for any endpoint (NapS 440 mg vs HYD+APAP 10 mg + 650 mg).<sup>1</sup>



## In the study, Aleve® was also better tolerated than HYD+APAP<sup>1</sup>

More treatment-related adverse events were reported with HYD+APAP (n=18) than Aleve® (n=1) and placebo (n=1), including nausea, vomiting, and dizziness.<sup>1</sup>

## The new study adds to the established evidence for Aleve® for minor dental pain

In 2 previous clinical studies for dental pain, Aleve® was proven to be stronger from the 3-hour mark onward and last longer than acetaminophen plus codeine (APAP + codeine). Both 8-hour studies (N=455) compared 1 dose of Aleve® 440 mg with 1 dose of APAP 600 mg + codeine 60 mg after surgical removal of 3 or 4 molars ( $\geq 1$  impacted).<sup>5,7</sup> In both studies:

- Patients who took Aleve® reported significantly reduced pain vs APAP + codeine ( $P < 0.05$ ) from the 3-hour mark onward<sup>5</sup>
- The 12-hour strength of Aleve® gave patients more sustained pain relief per dose, as demonstrated by a longer median time to remediation, vs patients on APAP + codeine ( $P < 0.05$ ), which is commonly prescribed every 4 hours as needed<sup>2,5,7</sup>
- Study population for Study 1: Aleve® (n=92), APAP + codeine (n=91), and placebo (n=47); and for Study 2: Aleve® (n=90), APAP + codeine (n=91), and placebo (n=44)<sup>5</sup>

## With the current opioid crisis, consider other options for treating minor dental pain

The United States accounts for 80% of the global opioid supply,<sup>8</sup> and opioids kill over 130 Americans every day.<sup>9</sup> Yet despite available pain relief options, opioids associated with dental treatment continue to pose significant risks to patients and their family members.<sup>8,10</sup>

A recent study shows that opioids are not associated with greater patient satisfaction for pain management after dental extractions.<sup>11</sup>

## “Recommend NSAIDs, like Aleve®, for non-opioid relief of minor dental pain, and you can help address the human and economic costs associated with the US opioid crisis.”<sup>1,4,12</sup>

—Dr. M. Ted Wong, DDS, MHA  
Board-Certified Prosthodontist  
Former Chief Dental Officer at UnitedHealthcare  
Former Chief of the US Army Dental Corps  
Bayer Paid Consultant

## Dental professional organizations recommend NSAIDs instead of opioids as first-line therapy for acute pain management<sup>13-15</sup>

The **American Dental Association** recommends NSAIDs as first-line therapy for acute pain management.<sup>13,14</sup>

The **American Association of Oral and Maxillofacial Surgeons** recommends NSAIDs as first-line therapy for acute pain management.<sup>15</sup>

The growing body of evidence offers a compelling argument for first-line use of an NSAID like Aleve® for dental pain, and the guidelines suggest ways of putting NSAIDs into practice.<sup>1,5,6,13-15</sup>

When prescribing any product, HCPs should always consider its efficacy and safety. Before any procedure requiring pain management, dentists should talk with patients about the benefits and risks of pain relief options.

“For dentists, this is an opportunity to play an active role in alleviating the ongoing opioid crisis,<sup>10</sup> and I encourage all of my colleagues to consider using effective non-opioid analgesics like Aleve® for minor dental pain.”<sup>12</sup>

—Dr. M. Ted Wong, DDS, MHA  
Bayer Paid Consultant

**References:** 1. Cooper SA, Desjardins PJ, Bertoch T, et al. Analgesic efficacy of naproxen sodium versus hydrocodone/acetaminophen in acute postsurgical dental pain: a randomized, double-blind, placebo-controlled trial. *Postgrad Med.* 2021. doi:10.1080/00325481.2021.2008180 2. Aleve® Caplets. Drug facts. Bayer HealthCare; April 2018. 3. US Department of Health and Human Services. Determination that a public health emergency exists. October 26, 2017. 4. Suda K, Zhou J, Rowan S, et al. Overprescribing of opioids to adults by dentists in the U.S., 2011-2015. *Am J Prev Med.* 2020;58(4):473-486. doi:10.1016/j.amepre.2019.11.006 5. Data on file, Bayer Consumer Health. 6. 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. 7. TYLENOL® with codeine Medication Guide. Janssen Pharmaceuticals, Inc.; October 2019. 8. Manchikanti L, Singh A. Therapeutic opioids: a ten-year perspective on the complexities and complications of the escalating use, abuse, and nonmedical use of opioids. *Pain Physician.* 2008;11(2 Suppl):S63-S88. 9. Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G. Drug and opioid-involved overdose deaths—United States, 2013-2017. *MMWR Morb Mortal Wkly Rep.* 2019;67(51-52):1419-1427. 10. Denisco RC, Kenna GA, O'Neil MG, et al. Prevention of prescription opioid abuse: the role of the dentist. *J Am Dent Assoc.* 2011;142(7):800-810. doi:10.14219/jada.archive.2011.0268 11. Nalliah RP, Sloss KR, Kenney BC, et al. Association of opioid use with pain and satisfaction after dental extraction. *JAMA Netw Open.* 2020;3(3):e200901. doi:10.1001/jamanetworkopen.2020.0901 12. Katz J, Smith S, Collins J, et al. Cost-effectiveness of nonsteroidal anti-inflammatory drugs and opioids in the treatment of knee osteoarthritis in older patients with multiple comorbidities. *Osteoarthritis Cartilage.* 2016;24(3):409-418. doi:10.1016/j.joca.2015.10.006 13. American Dental Association announces new policy to combat opioid epidemic. News release. American Dental Association. March 26, 2018. Accessed July 28, 2021. <https://www.prnewswire.com/news-releases/american-dental-association-announces-new-policy-to-combat-opioid-epidemic-300618928.html> 14. American Dental Association. Statement on the use of opioids in the treatment of dental pain. October 2016. Accessed October 14, 2021. <https://www.ada.org/en/advocacy/current-policies> 15. American Association of Oral and Maxillofacial Surgeons. Opioid prescribing: acute and postoperative pain management; 2020. White Paper. Accessed July 28, 2021. [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)

**ALEVE**

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.  
© 2021 Bayer December 2021 PP-AL-P-US-1603

