

WHAT'S NEW AT PAINWEEK 2026

At PAINWeek 2026, **TYLENOL[®] with Naproxen** debuts new Phase 3 clinical data demonstrating effective, long-lasting relief across two demanding post-surgical pain models.

These studies raise the bar on how efficacy is proven for OTC products and reflect one of the most rigorous clinical development programs in OTC pain, **spanning more than a decade and eight studies**.

CLINICAL DATA AT A GLANCE

Phase 3 Dental Pain Study

PAINWeek 2026 • Poster P083

Phase 3 third molar extraction study evaluating efficacy and speed of pain relief.

Delivered rapid, sustained 12-hour pain relief, outperforming acetaminophen and naproxen sodium alone.¹

Phase 3 Bunionectomy Study

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Phase 3 bunionectomy trial evaluating efficacy and tolerability over 48 hours.

First OTC product to demonstrate efficacy in the bunionectomy model, reducing opioid medication use by nearly 40% vs. placebo over 48 hours.²



Two additional posters complete the program: a pharmacokinetic and mechanistic rationale showing how two complementary mechanisms deliver powerful relief while using lower doses of each ingredient, and a national pharmacist survey underscoring the need for simpler, longer-lasting, multimodal OTC options.

BY THE NUMBERS

1ST & ONLY

FDA-approved OTC fixed-dose acetaminophen + naproxen sodium

8 STUDIES

clinical program spanning more than a decade

< 30 MIN

to onset of relief

12 HOURS

of relief in a single dose

~40%

less opioid rescue use (bunionectomy, 48 hrs vs placebo)³

3 YEARS

FDA-granted OTC exclusivity

ABOUT TYLENOL[®] WITH NAPROXEN

TYLENOL[®] with Naproxen is the first and only FDA-approved over-the-counter fixed-dose combination of 650 mg acetaminophen and 220 mg naproxen sodium. FDA-approved July 2026; indicated for adults and children 12 and over (for children under 12, consult a healthcare provider).

For full mechanism-of-action, dosing, and product details, see the companion TYLENOL[®] with Naproxen fact sheet on the media hub.

WHAT ELSE TYLENOL[®] WITH NAPROXEN IS DOING AT PAINWEEK

- **Breakfast symposium** with pain experts and patient-advocacy voices on non-opioid pain management.
- **Expert roundtable** convening clinicians on the evidence behind OTC combination therapy.
- **Interactive booth** showcasing the science behind the fixed-dose combination.

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¹Budnitz D, et al. Analgesic Effectiveness of a New Fixed-Dose Combination Acetaminophen/Naproxen Sodium: A Phase 3 Placebo-controlled, Randomized, Double-blind, Factorial Trial in Post-operative Dental Pain. PAINWeek 2026, Las Vegas, NV. Poster P083.

²Tharakan M, et al. A Phase 3 Multiple-dose Efficacy and Safety Trial of a Novel Fixed Dose Combination of Acetaminophen and Naproxen Sodium in a Post-surgical Bunionectomy Pain Model. PAINWeek 2026, Las Vegas, NV. Poster P081.