

TYLENOL[®] WITH NAPROXEN

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. Clinically proven and opioid-free, it delivers fast onset in under 30 minutes and 12 hours of relief in a single dose – providing a new, OTC option for the millions of Americans managing persistent pain.



How It Works

TYLENOL[®] with Naproxen combines two clinically established, complementary pain relievers into a single fixed-dose formulation, engineered to deliver both fast onset and long-lasting relief.

Acetaminophen works differently from NSAIDs. Rather than inhibiting prostaglandin synthesis at peripheral sites of inflammation, it is thought to act centrally to modulate pain perception.

Naproxen sodium is a non-steroidal anti-inflammatory drug (NSAID) that targets pain at the source of inflammation. NSAIDs work by reversibly inhibiting cyclooxygenase (COX) enzymes and reducing prostaglandin production, helping limit the generation of pain signals before they travel to the central nervous system.

Together, they provide: fast-acting acetaminophen alongside long-lasting naproxen sodium, supporting pain relief for 12 hours in a single dose.

Clinical Study Highlights

- **Backed by eight clinical studies** supporting FDA approval of the fixed-dose combination.
- **Superior pain relief** versus acetaminophen alone, naproxen sodium alone, and Aleve 220 mg.¹
- **Onset of relief in under 30 minutes** – clinically demonstrated fast action.
- **12 hours of relief in a single dose** – clinically demonstrated long-lasting duration.

Product Details

- **Age:** Indicated for adults and children 12 years and over. For children under 12 years, consult a healthcare provider.
- **Active Ingredients per Dose (2 pills):** 650 mg acetaminophen + 220 mg naproxen sodium.
- **Regulatory:** FDA-approved July 2026. Kenvue has been granted a three-year period of OTC exclusivity for this new formulation.
- **Important Safety Information:** Consumers should read and follow the Drug Facts label and consult a healthcare professional with any questions.

TYLENOL[®] with Naproxen will be coming soon to major U.S. retailers nationwide.

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¹Aleve is a trademark of Bayer Healthcare LLC