

Combogesic[®] (acetaminophen/ibuprofen) – New drug approval

- On March 1, 2023, the [FDA approved](#) AFT Pharmaceuticals' [Combogesic \(acetaminophen/ibuprofen\)](#), for the short-term management of mild to moderate acute pain.
- Combogesic is a combination tablet containing acetaminophen and ibuprofen, a nonsteroidal anti-inflammatory drug (NSAID).
- The efficacy of Combogesic was established in a study of 110 patients with post-procedural pain following surgical extraction of impacted wisdom teeth. Patients received Combogesic, ibuprofen alone, acetaminophen alone, or placebo. The primary endpoint was treatment differences in the time-adjusted Summed Pain Intensity Difference over the first 48 hours (SPID 0-48).
 - Three tablets of Combogesic provided greater pain reduction than placebo or comparable doses of acetaminophen or ibuprofen alone.
- Combogesic carries a boxed warning for hepatotoxicity, cardiovascular risk and gastrointestinal risk.
- Combogesic is contraindicated in
 - Patients with a known hypersensitivity to acetaminophen, ibuprofen, other NSAIDs, or to any of the excipients in this product
 - Patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs
 - The setting of coronary artery bypass graft surgery
- Additional warnings and precautions for Combogesic include hypertension; heart failure and edema; renal toxicity and hyperkalemia; anaphylaxis and other hypersensitivity reactions; exacerbation of asthma related to aspirin sensitivity; serious skin reactions; drug rash with eosinophilia and systemic symptoms; fetal toxicity; hematological toxicity; ophthalmological effects; aseptic meningitis; masking of inflammation and fever; and laboratory monitoring.
- The most common adverse reactions (≥ 2%) with Combogesic use were nausea, vomiting, headache, dizziness, somnolence, post-procedural hemorrhage, and swelling of the face.
- The recommended dose of Combogesic is 3 tablets every 6 hours as needed for pain relief, up to a maximum of 12 tablets per day.
- AFT Pharmaceuticals' launch plans for Combogesic are pending. Combogesic will be available as a film-coated tablet containing 325 mg acetaminophen and 97.5 mg ibuprofen.