

Ofirmev[®] (acetaminophen) – Updated Indications

- On January 27, 2017, the [FDA approved Ofirmev \(acetaminophen\)](#) injection for the management of mild to moderate pain in adult and pediatric patients 2 years and older, management of moderate to severe pain with adjunctive opioid analgesics in adult and pediatric patients 2 years and older, and for the reduction of fever in adult and pediatric patients.
 - Previously, the indications did not specify use in pediatric patients.
- The safety and effectiveness of Ofirmev for the treatment of acute pain in pediatric patients ≥ 2 years of age is supported by evidence from adequate and well-controlled studies of Ofirmev in adults and safety and pharmacokinetic data from adult and 483 pediatric patients across all age groups.
 - The effectiveness of Ofirmev for the treatment of acute pain in pediatric patients < 2 years of age has not been established.
- The safety and effectiveness of Ofirmev for the treatment of fever in pediatric patients, including premature neonates born at ≥ 32 weeks gestational age is supported by adequate and well-controlled studies of Ofirmev in adults, clinical studies in 244 pediatric patients ≥ 2 years of age, and safety and pharmacokinetic data from 239 patients < 2 years of age including neonates ≥ 32 weeks gestational age.
- Ofirmev carries a boxed warning for risk of medication errors and hepatotoxicity.
- The most common adverse reactions with Ofirmev use in pediatric patients were nausea, vomiting, constipation, and pruritus.
- The recommended dose of Ofirmev for children 2 – 12 years of age for the treatment of pain and fever is 15 mg/kg administered intravenously every 6 hours or 12.5 mg/kg every 4 hours to a maximum of 75 mg/kg per day. The minimum dosing interval is 4 hours.
- The recommended dose of Ofirmev for the treatment of fever in neonates born ≥ 32 weeks gestational age, up to 28 days chronological age is 12.5 mg/kg every 6 hours, to a maximum daily dose of acetaminophen of 50 mg/kg per day. The minimum dosing interval is 6 hours.
- The recommended dose of Ofirmev for the treatment of fever in infants 29 days to 2 years of age is 15 mg/kg every 6 hours, to a maximum daily dose of acetaminophen of 60 mg/day. The minimum dosing interval is 6 hours.
- Refer to the Ofirmev drug label for specific dosing recommendations for adults and adolescents ≥ 13 years of age.

- Exceeding the maximum mg/kg daily dose of acetaminophen may result in hepatic injury, including the risk of liver failure and death. To avoid the risk of overdose, the total amount of acetaminophen from all routes and from all sources should not exceed the maximum recommended dose.



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