

Ofirmev® (acetaminophen) – First-time generic

- On December 7, 2020, <u>Leucadia Pharmaceuticals</u> and Auromedics/Aurobindo launched <u>AP-rated</u> generic versions of Mallinckrodt's <u>Ofirmev (acetaminophen)</u> intravenous solution.
 - On March 22, 2016, Sandoz received FDA approval of an <u>AP-rated</u> generic version of Ofirmev. Launch plans are pending.
 - On August 7, 2020, Mylan received FDA approval of an <u>AP-rated</u> generic version of Ofirmev. Launch plans are pending.
- Ofirmev is approved for the management of mild to moderate pain in adult and pediatric patients 2
 years and older; the management of moderate to severe pain with adjunctive opioid analgesics in
 adult and pediatric patients 2 years and older; and the reduction of fever in adult and pediatric
 patients.
- Ofirmev carries a boxed warning for risk of medication errors and hepatotoxicity.



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