

FIRST TIME GENERIC APPROVAL

Brand Name	Ofirmev®
Generic Name	acetaminophen
Drug Manufacturer	Leucadia Pharmaceuticals under Custopharm Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic/New Strength (1,000mg/100mL)

FDA APPROVAL DATE

June 13, 2016

LAUNCH DATE

December 4, 2020

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 202605

DISPENSING RESTRICTIONS

None

Overview

INDICATION FOR USE

Acetaminophen injection for intravenous use is indicated 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;
- Reduction of fever in adult and pediatric patients.

MECHANISMS OF ACTION

The precise mechanism of the analgesic and antipyretic properties of acetaminophen is not established but is thought to primarily involve central actions.

DOSE FORM AND STRENGTH

- Injection: Each 100 mL bag contains 1,000 mg acetaminophen (10 mg/mL)

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DOSE & ADMINISTRATION

- Acetaminophen injection may be given as a single or repeated dose.
- Acetaminophen injection should be administered only as a 15-minute intravenous infusion.

Adults and Adolescents Weighing 50 kg and Over:

- 1,000 mg every 6 hours or 650 mg every 4 hours to a maximum of 4,000 mg per day. Minimum dosing interval of 4 hours.

Adults and Adolescents Weighing Under 50 kg:

- 15 mg/kg every 6 hours or 12.5 mg/kg every 4 hours to a maximum of 75 mg/kg per day. Minimum dosing interval of 4 hours.

Children:

- Children 2 to 12 years of age: 15 mg/kg every 6 hours or 12.5 mg/kg every 4 hours to a maximum of 75 mg/kg per day. Minimum dosing interval of 4 hours.

Neonates and Infants:

- Neonates including premature neonates born at ≥ 32 weeks gestational age to 28 days chronological age, 12.5 mg/kg every 6 hours to a maximum of 50 mg/kg per day. Minimum dosing interval of 6 hours.
- Infants (29 days to 2 years of age): 15 mg/kg every 6 hours to a maximum of 60 mg/kg per day. Minimum dosing interval of 6 hours.

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