NOW APPROVED

NEW
OFIRMEV™
(acetaminophen) injection

The first and only IV formulation of acetaminophen in the US

Improved pain relief, reduced opioid consumption[1]

- Significant pain relief*[1]
  - –OFIRMEV 1 g + PCA morphine demonstrated significant pain relief vs placebo + PCA morphine ($P<0.05$ over 6 h)[1]
  - –OFIRMEV 1 g + PCA morphine showed greater reduction in pain intensity over 24 h (SPID24)† compared to placebo + PCA morphine ($P<0.001$)[2]
- Reduced opioid consumption*[1]
  - –OFIRMEV 1 g + PCA morphine significantly reduced morphine consumption vs placebo + PCA morphine (–46% over 6 h, $P<0.01$; –33% over 24 h, $P<0.01$)[1]
  - –The clinical benefit of reduced opioid consumption was not demonstrated
- Improved patient satisfaction*[1,2]
  - –OFIRMEV 1 g + PCA morphine significantly improved patient satisfaction vs placebo + PCA morphine at 24 h ($P=0.004$)‡[1,2]
- The first IV antipyretic approved for children ≥2 years old[3]
  - –Significant fever reduction 30 minutes after initiating infusion[2]
- Established safety profile and well tolerated in clinical trials[1-3]

OFIRMEV is indicated for the:

- Management of mild to moderate pain
- Management of moderate to severe pain with adjunctive opioid analgesics
- Reduction of fever

OFIRMEV is contraindicated in patients with severe hepatic impairment, severe active liver disease or with known hypersensitivity to acetaminophen or to any of the excipients in the formulation.

The most common adverse reactions in patients treated with OFIRMEV were nausea, vomiting, headache, and insomnia in adult patients and nausea, vomiting, constipation, pruritus, agitation, and atelectasis in pediatric patients.

Dosing

Dosing of OFIRMEV for adults, adolescents, and children ≥2 years old[3]

Age group	Dosing interval	Maximum single dose	Maximum total daily dose of acetaminophen (by any route)
Adults and adolescents (≥13 years old) **≥50 kg**	Q6h	1000 mg (100 mL)*	4000 mg
Adults and adolescents (≥13 years old) **<50 kg**	Q6h	*Weight-based dose:* 15 mg/kg	75 mg/kg†
Children ≥2 to 12 years old			

- Minimum dosing interval is Q4h
- For instructions regarding Q4h dosing, please see full Prescribing Information
- No dose adjustment is required when transitioning to oral acetaminophen in adults and adolescents
- OFIRMEV should be administered only as a 15-minute infusion. Administer only as directed.
- Do not exceed the maximum daily dose of acetaminophen

*Each mL contains 10 mg of OFIRMEV.
†Maximum daily dose up to 3750 mg.

Product information

Ordering information

NDC	Minimum order quantity	WAC
43825-102-01	1 case (24 vials)	$258.00/case

Wholesaler information

Wholesaler	Order number
AmerisourceBergen	065488
Cardinal	4364030
McKesson	1656800

OFIRMEV storage and handling

- OFIRMEV is supplied in a 100-mL glass vial containing 1000 mg acetaminophen (10 mg/mL)
- OFIRMEV should be stored at 20 °C to 25 °C (68 °F to 77 °F) [See USP Controlled Room Temperature]
- For single use only. The product should be used within 6 hours after opening.
- Vial dimensions: 1.9" × 4.3"

Click here to see full Prescribing Information.

Important Safety Information

OFIRMEV should be administered only as a 15-minute infusion.

Do not exceed the maximum recommended daily dose of acetaminophen.

Administration of acetaminophen by any route in doses higher than recommended may result in hepatic injury, including the risk of severe hepatotoxicity and death.

Acetaminophen should be used with caution in patients with the following conditions: hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia, or severe renal impairment.

Discontinue OFIRMEV immediately if symptoms associated with allergy or hypersensitivity occur.

Do not use in patients with acetaminophen allergy.

The antipyretic effects of OFIRMEV may mask fever in patients treated for postsurgical pain.

*Randomized, double-blind, placebo-controlled, single- and repeated-dose 24-h study (n=101). Patients received OFIRMEV 1 g + PCA morphine or placebo + PCA morphine the morning following total hip or knee replacement surgery. Primary endpoint: pain relief measured on a 5-point verbal scale over 6 h. Morphine rescue was administered as needed.

†SPID24=sum of pain intensity differences, based on VAS score, from baseline, at 0 to 24 h.

‡Subjects were asked to evaluate the study treatments, overall, using a 4-point categorical scale.

References: 1. Sinatra RS, Jahr JS, Reynolds LW, Viscusi ER, Groudine SB, Payen-Champenois C. Efficacy and safety of single and repeated administration of 1 gram intravenous acetaminophen injection (paracetamol) for pain management after major orthopedic surgery. *Anesthesiology.* 2005;102:822-831. **2.** Data on file. Cadence Pharmaceuticals, Inc. **3.** OFIRMEV™ (acetaminophen) injection prescribing information. Cadence Pharmaceuticals, Inc.

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