Acetaminophen

Injection for Intravenous Use

freeflex®

Fresenius Kabi offers a growing portfolio of premix medications in innovative **free*flex***® bags not made with PVC or DEHP. We are committed to bringing quality medicines and technologies to clinicians, when and where they need them most.

Fill Volume	Product Code	NDC
100 mL	434100	63323-434-00

Strength	Concentration	Units/case
1,000 mg per 100 mL	10 mg per mL	20

UPC
(01) 30363323434008 (21) 0000000000000

Wholesaler/Distributor Information			
Cardinal	Cencora	McKesson	Morris & Dickson
5690516	10252121	1585389	921924

- Preservative-free
- Phthalate-free
- Bar-coded
- Container closure is not made with natural rubber latex
- Not made with PVC/DEHP

WARNING: RISK OF MEDICATION ERRORS AND HEPATOTOXICITY

See full prescribing information for complete boxed warning

Take care when prescribing, preparing, and administering Acetaminophen Injection to avoid dosing errors which could result in accidental overdose and death.

Acetaminophen Injection contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits, and often involve more than one acetaminophen-containing product.

Please see Important Safety Information on the following page.

For more information or to place an order, contact your Sales Representative or call Customer Service at 1.888.386.1300 | freseniuskabipremixbags.com

FRESENIUS KABI

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
Phone: 1.888.386.1300
www.fresenius-kabi.com/us

2059-ACETM-02-08/21 v5.0

INDICATIONS AND USAGE

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 2 years and older.

IMPORTANT SAFETY INFORMATION

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Acetaminophen is contraindicated:

- In patients with known hypersensitivity to acetaminophen or to any of the excipients in the IV formulation.
- In patients with severe hepatic impairment or severe active liver disease.

Administration of acetaminophen in doses higher than recommended (by all routes of administration and from all acetaminophen-containing products including combination products) may result in hepatic injury, including the risk of liver failure and death.

Use caution when administering acetaminophen in patients with the following conditions: hepatic impairment or active hepatic disease, in cases of alcoholism, chronic malnutrition, severe hypovolemia, or severe renal impairment (creatinine clearance ≤ 30 mL/min).

Rarely, acetaminophen may cause serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Discontinue acetaminophen immediately at the first sign of skin rash.

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Hypersensitivity and anaphylaxis associated with the use of acetaminophen have been reported. Clinical signs included swelling of the face, mouth, and throat, respiratory distress, urticaria, rash, and pruritis. Discontinue acetaminophen injection immediately upon occurrence of signs or symptoms associated with allergy or hypersensitivity. Do not use acetaminophen injection in patients with acetaminophen allergy.

The antipyretic effects of acetaminophen injection may mask fever.

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

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Substances that induce or regulate hepatic cytochrome enzyme CYP2E1 may alter the metabolism of acetaminophen and increase its hepatotoxic potential.

Chronic oral acetaminophen use at a dose of 4,000 mg/day has been shown to cause an increase in international normalized ratio (INR) in some patients who have been stabilized on sodium warfarin as an anticoagulant.

Pediatric Use: The effectiveness of acetaminophen for the treatment of acute pain in pediatric patients younger than 2 years of age has not been established. The safety and effectiveness of acetaminophen in pediatric patients older than 2 years of age is supported by evidence from adequate and well controlled studies in adults with additional safety and pharmacokinetic data for this age group.

Geriatric Use: No overall differences in safety or effectiveness were observed between geriatric and younger subjects.

Hepatic Impairment: Acetaminophen is contraindicated in patients with severe hepatic impairment or severe active liver disease and should be used with caution in patients with hepatic impairment or active liver disease.

Renal Impairment: In cases of severe renal impairment, longer dosing intervals and a reduced total daily dose of acetaminophen may be warranted.

This Important Safety Information does not include all the information needed to use Acetaminophen Injection safely and effectively. Please see accompanying full prescribing information for Acetaminophen Injection, including BOXED WARNING. Full prescribing information is also available at www.fresenius-kabi.com/us.

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