

Hikma - Recall of acetaminophen injection

- On July 22, 2024, <u>Hikma announced</u> a consumer level recall of one lot of <u>acetaminophen</u> injection 1000 mg/100 mL (10 mg/mL) due to the potential presence of a bag labelled <u>dexmedetomidine</u> injection (400 mcg/100 mL) inside the overwrap that is labeled acetaminophen injection, 1000 mg/100 mL, (10 mg/mL).
- Endo shipped the recalled lot from April 2024 to June 2024.

| Product Description | NDC numbers | Lot number (Exp Date) |
|---|-------------------------------|-----------------------|
| Acetaminophen injection, 1,000 mg per 100 mL (10 mg/mL) | 0143-9386-10; 0143-9386-01 | 24070381 (9/2025) |

- Acetaminophen injection is indicated 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.
- Dexmedetomidine is indicated for intensive care unit sedation and procedural sedation.
- If the provider does not identify the drug inside the acetaminophen overwrap as dexmedetomidine and administers the drug to a patient, there are multiple potential adverse outcomes that may result including varying degrees of sedation, bradypnea, bradycardia, hypertension, and hypotension or more serious and potentially life-threatening outcomes.
- To date, Hikma has received one report of an adverse event.
- Anyone with the affected lot on hand should stop distribution and return product. Patients should not use recalled medicine and contact their healthcare provider with any medical related questions.
- Contact Hikma by phone at 1-800-631-2174 or by email at <u>usrecall@hikma.com</u> for questions regarding the recall.
- Contact Inmar (appointed company for Hikma) by phone at 1-877-890-0765 or email at rxrecalls@inmar.com for product return.



At Optum, we help create a healthier world, one insight, one connection, one person at a time. All Optum trademarks and logos are owned by Optum, Inc., in the U.S. and other jurisdictions. All other trademarks are the property of their respective owners. This document contains information that is considered proprietary to Optum Rx and should not be reproduced without the express written consent of Optum Rx. RxNews® is published by the Optum Rx Clinical Services Department.