Hikma – Recall of acetaminophen injection

- On July 22, 2024, Hikma announced a consumer level recall of one lot of acetaminophen injection 1000 mg/100 mL (10 mg/mL) due to the potential presence of a bag labelled dexmedetomidine 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 **usrecall@hikma.com** 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.