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Press Release

# Hikma Pharmaceuticals USA Inc. Extends Voluntary Nationwide Recall of One Lot of Acetaminophen Injection, 1000mg/100mL, (10mg/mL) Bags Due to an Individual Unit of Acetaminophen Overwrap Found to Have Contained a Labelled Bag of Dexmedetomidine HCL Injection (400mcg/100mL)

**London, July 22, 2024** – Hikma Pharmaceuticals PLC (Hikma, Group), today announces that its subsidiary Hikma Pharmaceuticals USA, Inc. is extending its voluntary recall of one lot (listed below) of Acetaminophen Injection, 1000mg/100mL, (10mg/mL) to the consumer/user level. The product is being recalled due to the potential presence of a bag labelled Dexmedetomidine HCL Injection (400mcg/100mL) inside the overwrap that is labelled Acetaminophen Injection, 1000mg/100mL, (10mg/mL).

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.

On July 8, 2024, Hikma voluntarily initiated a retail level recall of Acetaminophen Injection 1000mg/100mL(10mg/mL), lot 24070381.

The lot being recalled was manufactured on 3/19/2024.

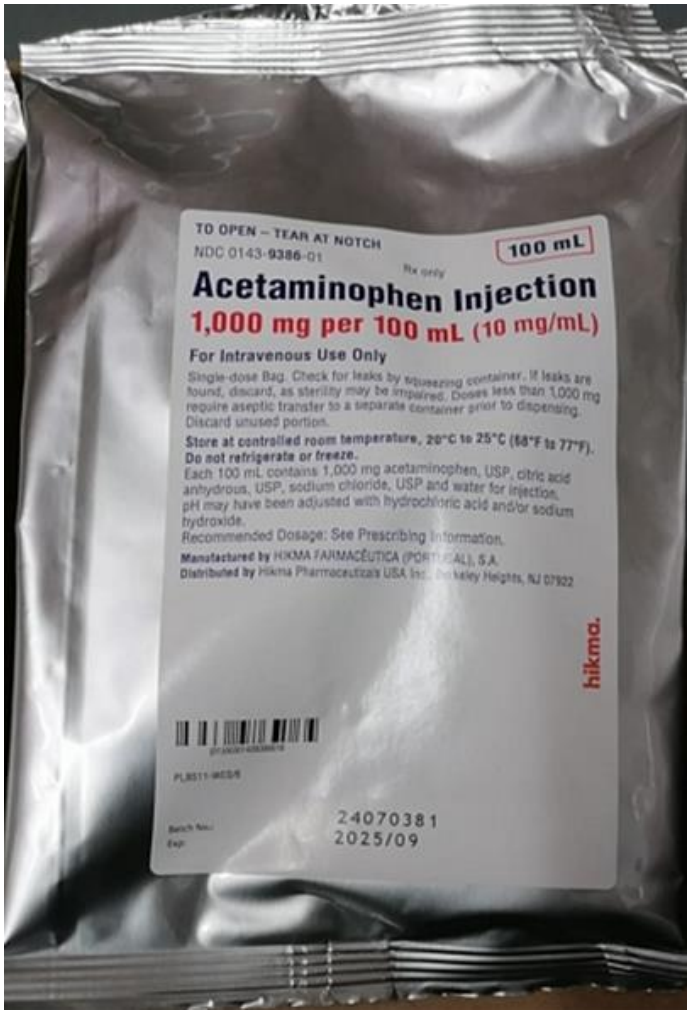
Acetaminophen Injection is a sterile, nonpyrogenic ready-to-use solution, available in IV bags for intravenous infusion. Each 100 mL contains 1,000 mg acetaminophen, USP, 193 mg anhydrous citric acid, USP, sodium chloride, USP (tonicity agent) and water for injection. pH may be adjusted with hydrochloric acid and/or sodium hydroxide. 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.

The affected lot number and expiration date being recalled is as follows:

| NDC | Product Name and Strength | Size | Lot Number | Expiration Date |
|---|---|---|---|---|
| 0143-9386-10 0143-9386-01, Individual bag overwrap | Hikma brand Acetaminophen Injection USP, 1,000 mg per 100 mL (10 mg/mL) | 100mL bag | 24070381 | Sep-2025 |

The product can be identified by name and NDC and lot code, which are clearly stated on the overwrap of the product label, along with Hikma Pharmaceuticals USA Inc. name and address. Images of the labels are included below:

Acetaminophen Injection individual Overwrap Label:




Acetaminophen Injection Shipper Label

The product was distributed to Hikma's direct customers nationwide. Hikma notified its direct customers as part of the recall on July 8, 2024, asking them to locate and remove the recalled product from distribution channels and return the recalled lot to Hikma's recall service provider (Inmar Rx Solutions Inc.). Hikma also requested the direct customers to notify their direct retail customers to whom this affected product lot was distributed. Hikma is now extending the recall to the consumer/user level and asking customers at medical level facilities to locate and remove the recalled product from their channels and return the recalled lot.

For recall inquiries, please contact Hikma using the information provided below:

| **Hikma Contact** | **Contact Information** | **Areas of Support** |
|---|---|---|
| Hikma Pharmaceuticals USA Inc. – Customer Service | (P): (800) 631-2174<br>(E): usrecall@hikma.com<br>(F): (732) 542-0940<br>Hours of operation, M-F: 8:00am-6pm (EST) | Recall related inquires |
| Inmar Rx Solutions, Inc. (Hikma 3rd Party Recall Service Provider) | Mail to:<br><br>Inmar RX Solutions, Attention recall Coordinator, 3845 Grand Lakes Way, Grand Prairie, TX 75050<br>(E): HikmaEvent@Inmar.com<br>(F): 1-817-868-5362 | Product Returns |

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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