

September 1, 2026

Important Correction of Drug Information

Subject: Correction of Information Related to the Expiration Date Encoded in the 2D Barcode on Unit-Dose Blister Drug Products

Dear Health Care Provider:

The purpose of this letter is to correct information regarding the expiration date encoded within the two-dimensional (2D) barcode on the unit-dose blister presentation of the list of drug products with corresponding NDC number and batch number, (See Table 1 below) distributed by Hikma Pharmaceuticals USA Inc. (A Hikma Company).

It has been identified that the **expiration date encoded in the 2D barcode on the unit-dose blister cards does not match the expiration date printed in human-readable format on the blister card and carton labeling**. This communication is being provided to ensure that health care providers, pharmacists, and other healthcare personnel have accurate information regarding the affected products and their appropriate shelf-life.

Description of the Issue

The affected unit-dose blister cards contain a 2D barcode with an incorrect encoded expiration date. When scanned using barcode-enabled medication management systems, electronic health records, automated dispensing cabinets, or bedside medication administration systems, the expiration date displayed may differ from the expiration date printed in human-readable text on the blister package. **Specifically, the human-readable expiration date printed on the packaging is the correct FDA-approved expiration date.** The expiration date encoded in the 2D barcode is 1 month longer than the printed expiration date. Product identity, National Drug Code (NDC), lot number, strength, dosage form, and other product information remain accurate. No product quality, safety, efficacy, sterility, potency, or stability concerns have been identified as a result of this issue.

Verified Information:

For the subject products, the **human-readable expiration date printed on the unit-dose blister packaging and outer carton should be considered the correct expiration date** for dispensing, administration, inventory management, and product disposition purposes. Although the expiration date encoded within the 2D barcode is incorrect; Hikma has stability data to support that the products are stable and expected to meet all product specifications through the additional 1-month of shelf-life.

Recommended Actions for Health Care Providers and Pharmacies:

Healthcare providers, pharmacists, pharmacy technicians, and inventory management personnel should:

- Verify expiration dates using the **human-readable expiration date** printed on the blister package and outer carton.
- Continue to dispense and administer affected products according to approved labeling and established institutional procedures.
- Review inventory management systems that may rely on scanned barcode expiration date information and update as appropriate.
- Evaluate whether local barcode-driven workflows require temporary manual verification of expiration dates for affected lots.
- Inform appropriate personnel within your organization, including pharmacy operations, medication safety, and information technology staff, as needed.

Product Indications:

The affected products remain approved for their respective FDA-approved indications. This notification does not alter the approved indication, dosage and administration, contraindications, warnings and precautions, or other prescribing information for any affected product. For full prescribing information see Table 1 below.

Important Safety Information:

No adverse events or patient safety concerns attributable to the barcode expiration-date discrepancy have been identified to date. However, reliance on the incorrect expiration date encoded in the barcode could potentially result in:

- Continued retention of product beyond its approved expiration date if the encoded date is later than the correct expiration date
- Inventory management discrepancies within electronic medication systems
- Healthcare facilities should ensure that inventory control decisions are based on the human-readable expiration date until corrected inventory is available

Reporting Adverse Events:

Health care providers and patients are encouraged to report adverse events in patients taking any of the drug products listed below to Hikma at 1-877-845-0689 or 1-800-631-2174.

Adverse events, medication errors, or quality problems experienced with the use of these drug products may also 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.

You may also contact our medical information department at 1-877-845-0689 or 1-800-631-2174 if you have any questions about the information contained in this letter or the safe and effective use of any of these drug products.

This letter is not intended as a complete description of the benefits and risks related to the use of these products. Please refer to the full prescribing information linked below in Table 1 (and medication guide, if there is a medication guide for the product, or any other approved patient information).

For additional information, please call Hikma at 1-877-845-0689 or 1-800-631-2174 or visit www.hikma.com/en-us/products/

Sincerely,

Respectfully,
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Table 1: Hikma Pharmaceuticals USA Inc. Drug Products and Batch Numbers with Affected 2D Barcode

Drug Product Name	NDC Number	Batch Number	Expiration Date	2D Barcode Expiration	Prescribing Information
Codeine Sulfate Tablets, USP, 15 mg	0054-0243-24	AC6576A	2027-APR	2027-MAY	DailyMed - CODEINE SULFATE tablet
Codeine Sulfate Tablets, USP, 30 mg	0054-0244-24	AC6193A	2027-APR	2027-MAY	
Flecainide Acetate Tablets, USP, 100 mg	0054-0011-20	AC7540B	2028-MAY	2028-JUN	DailyMed - FLECAINIDE ACETATE tablet
Flecainide Acetate Tablets, USP, 50 mg	0054-0010-20	AC6693B	2027-OCT	2027-NOV	
Lithium Carbonate Capsules, USP, 150 mg	0054-8526-25	AC7143A	2028-JAN	2028-FEB	DailyMed - LITHIUM CARBONATE tablet LITHIUM CARBONATE capsule, gelatin coated LITHIUM solution
Lithium Carbonate Capsules, USP, 300 mg	0054-8527-25	AC7094A	2028-JAN	2028-FEB	
Lithium Carbonate Tablets, USP, 300 mg	0054-8528-25	AC7023A	2027-OCT	2027-NOV	
Methadone Hydrochloride Tablets, USP, 10 mg	0054-0710-20	AC8153A	2029-APR	2029-MAY	DailyMed - METHADONE HYDROCHLORIDE tablet
		AC7146A	2029-FEB	2029-MAR	
Methadone Hydrochloride Tablets, USP, 5 mg	0054-0709-20	AC8154A	2029-APR	2029-MAY	
Morphine Sulfate Tablets, 15 mg	0054-0235-24	AC6191B	2027-APR	2027-MAY	DailyMed - MORPHINE SULFATE tablet
Alvimopan Capsules, 12 mg (GSMS)	51407-870-33	AC6038C	2027-09	2027-10	DailyMed - ALVIMOPAN capsule
Alvimopan Capsules, 12 mg	0054-0668-82	AC6535A	2027-OCT	2027-NOV	DailyMed - ALVIMOPAN capsule