Baxter

SAFETY ALERT

November 13, 2026

IMPORTANT DRUG INFORMATION

Subject: Potential Aluminum Vial Seal Defect in One (1) lot of DOXIL (DOXOrubicin hydrochloride liposome injection. 50 mg/25 mL, NDC 0338-9665-01) in a Single-Dose Vial

Dear Healthcare Provider or Distributor:

To prevent shortage of this drug, Baxter Healthcare Corporation is coordinating with the United States Food and Drug Administration (FDA) to communicate this important safety information regarding DOXIL (DOXOrubicin hydrochloride liposome injection) 50 mg / 25 mL. Baxter has received customer reports of improperly crimped aluminum vial seals in which removal of the flip-off cap resulted in the entire vial closure assembly, including the aluminum seal and rubber stopper, detaching from the vial and leaving the vial open. The affected lot number was distributed beginning on 8/12/2026 in the United States.

DOXIL liposomal infusion is indicated for the following:

- Treatment of patients with ovarian cancer whose disease has progressed or recurred after platinum-based chemotherapy.
- Treatment of AIDS-related Kaposi's sarcoma in patients after failure of prior systemic chemotherapy or intolerance to such therapy.
- In combination with bortezomib, treatment of patients with multiple myeloma who have not previously received bortezomib and have received at least one prior therapy.

Affected Product

Product Code	Product Description	Lot Number	Expiration Date	NDC Number
2321B0332	DOXIL (DOXOrubicin hydrochloride liposome injection), 50mg / 25mL (2mg / mL) Single-Dose Vial.	5H020FA / 5H020F *	31-Mar-2027	0338-9665-01

*Please note lot number 5H020FA is printed on the carton label and lot number 5H020F is printed on the container label.

Hazard Involved

Inadequate crimping of the aluminum vial seal may compromise container closure integrity and result in unintended occupational exposure or a delay in therapy. In the unlikely event that compromised product is administered, serious infection, including sepsis, organ failure, or death, could occur. The overall risk is considered low because the defect is readily visible and is expected to be identified during routine inspection and preparation. To date, Baxter has not received any reports of adverse events related to this issue.

Actions to be Taken by Customers

1. During pharmacy preparation, inspect the vials before use and following removal of the flip-off cap. **If a vial exhibits any closure abnormalities, leakage, or signs of compromised integrity, please remove it from use before administration and contact Baxter Product Surveillance to report the issue.** If no defects are observed, the product can be used.



Figure 1. Example of vial closure abnormality



Figure 2. Example of no vial closure abnormality

2. If you received this communication directly from Baxter, please acknowledge receipt of this notification by following the instructions in the corresponding email, even if you have no remaining inventory. Acknowledging receipt will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from Accenture LLP on behalf of Baxter to confirm your receipt of this notification.
3. If you purchased this product from a distributor or wholesaler, you do not need to respond to Baxter directly. If a response is requested by your distributor or wholesaler, please respond to them according to their instructions.
4. Please forward a copy of this communication to the director of pharmacy, director of nursing, director of purchasing, facility risk manager, and any other departments within your institution who use the affected product.
5. If you are a dealer, wholesaler, or distributor/reseller that distributed any affected product to other facilities, please disseminate this notice to your customers, and check the associated box on the customer portal.

Reporting Product Quality Complaints, Adverse Events, or Medication Errors

Health care providers and patients are encouraged to report any product quality complaints, adverse events, and medication errors regarding DOXIL (DOXOrubicin hydrochloride liposome injection) 50 mg / 25 mL, to Baxter Product Surveillance at the Baxter product feedback portal at: https://productfeedback.baxter.com, or emailing Baxter at: corporate product_complaints_round_lake@baxter.com.

Any product quality complaints, adverse events, and medication errors experienced with the use of this product may also be reported to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

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

For general questions regarding this communication, please contact Baxter Healthcare Center for Service at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday.

This letter is not intended to be a complete description of the benefits and risks related to the use of DOXIL (DOXOrubicin hydrochloride liposome injection) 50 mg / 25 mL. Please refer to the full prescribing information at DailyMed - DOXIL- doxorubicin hydrochloride injection, suspension, liposomal.

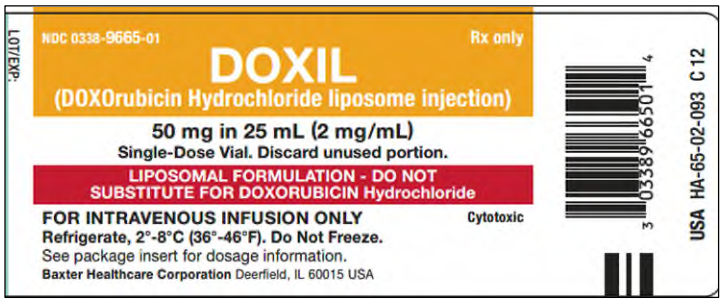
Baxter is committed to patient safety and to providing safe high-quality products. We thank you for your attention to this important information.

Sincerely,

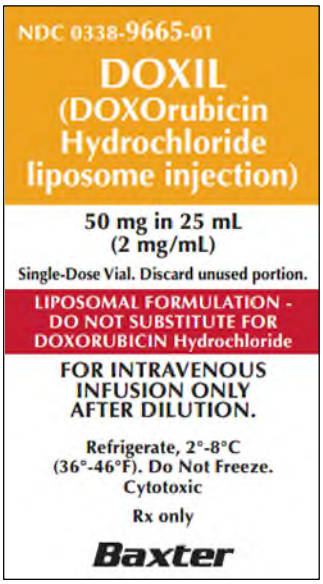
Nicolas Vanhaelen

Nicolas Vanhaelen
Director, Product Quality
Baxter Healthcare Corporation

For ease of product identification, refer to product photos below.



Container Label



Carton Label