CAELYX (doxorubicin pegylated liposomal), 50 mg/25 mL (2 mg/mL) for injection, single-dose vial:

Vial stopper and seal may detach during cap removal, potentially compromising sterility and resulting in unintended occupational exposure

October 30, 2026

Dear Healthcare Professional

Baxter Holding B.V. in agreement with the European Medicines Agency (EMA) and the {*national competent authority}* would like to inform you of the following.

Summary

- **There have been reports of improperly crimped aluminium vial seals in the CAELYX batches listed in the table below (the metal seal may not be securely fastened around the vial neck)**.
- **Removal of the flip-off cap may cause the aluminium seal and rubber stopper to detach, leaving the vial open and compromising sterility. As a result, the risk of microbial contamination and infection may be increased.**
- **The affected batches were distributed in <Member State> from <dd/mm/yy> to <dd/mm/yy>.**
- **Before use, and again after removing the flip-off cap, visually inspect each vial for closure abnormalities, leakage, or other signs of compromised container integrity. The aluminium seal and rubber stopper should remain in position.**
- **Do not use a vial with an observed defect. Remove it from use and contact Baxter for further guidance.**
- **Vials with no visible defects may be used as intended.**

Ensure that relevant pharmacy, nursing, medical, and distribution personnel are informed of this communication and the required inspection.

Background

Caelyx is a pegylated liposomal doxorubicin cytotoxic product indicated*:*
- As monotherapy for patients with metastatic breast cancer, where there is an increased cardiac risk.
- For treatment of advanced ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen.

- In combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.
- For treatment of AIDS-related Kaposi's sarcoma (KS) in patients with low CD4 counts (< 200 CD4 lymphocytes/mm3) and extensive mucocutaneous or visceral disease. Caelyx pegylated liposomal may be used as first-line systemic chemotherapy, or as second line chemotherapy in AIDS-KS patients with disease that has progressed with, or in patients intolerant to, prior combination systemic chemotherapy comprising at least two of the following agents: a vinca alkaloid, bleomycin and standard doxorubicin (or other anthracycline).

Inadequate crimping of the aluminium vial seal may compromise container closure integrity and sterility. This could result in unintended occupational exposure to the product or a delay in treatment if the vial cannot be used. In the unlikely event that a compromised product is administered, serious infections, including sepsis, which can result in organ failure, or death, could occur. However, the overall risk to both patients and healthcare professionals 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.

Images of the defect:

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Fig 1. Example of vial closure abnormality

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Fig 2. Example of no vial closure abnormality

Table 1: List of affected product lots. (to be adapted locally)

Product Code	Product Description	Lot Number	Expiration Date
0321B0300	CAELYX 50 mg/25 mL (Germany)	5H020AA	31-Mar-2027
		5I021B	30-Apr-2027
		5J023C	30-Sep-2027
		5J023E	30-Sep-2027
0321B0300	CAELYX 50 mg/25 mL (Austria)	5I021B	30-Apr-2027
2321B0301		5H020CA	31-Mar-2027
		5H020I	31-Mar-2027
		5J023F	30-Sep-2027
2321B0305	CAELYX 50 mg/25 mL (France)	5I021E	30-Apr-2027

2321B0307	CAELYX 50 mg/25 mL (Ireland)	5J023H	30-Sep-2027
2321B0308	CAELYX 50 mg/25 mL (Italy)	5J023B	30-Sep-2027
2321B0310	CAELYX 50 mg/25 mL (Belgium/Netherlands)	5H020G	31-Mar-2027
		5I021C	30-Apr-2027
2321B0332	DOXIL 50 mg/25 mL (Belgium/Italy)	5H020FA	31-Mar-2027
2321B0314	CAELYX 50 mg/25 mL (Czech Republic/Slovakia)	5H020EA	31-Mar-2027
2321B0320	CAELYX 50 mg/25 mL (Romania)	5H020DA	31-Mar-2027
		5H020H	31-Mar-2027
2321B0323	CAELYX 50 mg/25 mL (Poland)	5H020BA	31-Mar-2027
		5J023G	30-Sep-2027
2321B0336	CAELYX 50 mg/25 mL (Hungary/Croatia/Slovenia)	5J023D	30-Sep-2027

Call for reporting

Healthcare professionals are asked to report any observed and/or suspected product quality defects and any suspected adverse drug reactions to Baxter and, as applicable, through the relevant national reporting system, in accordance with local reporting requirements < include the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>.

Company contact point

< Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>