

Important Prescribing Information

July 2025

Subject: Introducing New Preparation and Storage Instructions and Extension of Expiration Dates for Certain Lots of CYTALUX® (pafolacianine) injection

Dear Health Care Provider:

On Target Laboratories would like to alert providers of a change in storage and preparation instructions and an extension of expiration dates for certain lots of CYTALUX (pafolacianine) injection. CYTALUX is an FDA approved imaging agent indicated as an adjunct for the intraoperative identification of ovarian cancer and cancer in the lung.

Summary of Changes to Preparation and Storage Instructions:

Previous Instructions	New Instructions
Thawed CYTALUX vials may be refrozen once	Thawed CYTALUX vials may be refrozen three times

These revisions are intended to include clarification and allow for needed flexibility in scheduling patient arrival for drug administration prior to surgical procedures as well as ensuring that the quality of the product is not compromised in the event there are delays.

Detailed Updated Preparation and Storage Instructions:

3. CYTALUX vials should be stored and thawed in the original carton protected from light.
 - a. Remove carton containing one single vial of CYTALUX from freezer and record the date, time and thawing condition on the carton.
 - b. Thaw at room temperature between 20°C to 25°C (68°F to 77°F) for at least 60 minutes or under refrigerated conditions between 2°C to 8°C (36°F to 46°F) for at least 6 hours. When thawed under refrigerated conditions, allow the vial to stand at room temperature for 15 minutes before dilution.
 - c. Once thawed, an individual CYTALUX vial may be stored at room temperature between 20°C to 25°C (68°F to 77°F) for a maximum single period of 24 hours or under refrigerated conditions between 2°C to 8°C (36°F to 46°F) for a maximum single period of up to 30 days, prior to preparation for infusion.
 - d. If CYTALUX vial is not used within the maximum single period at either room temperature or under refrigerated conditions, the vial may be refrozen up to three times.
 - e. If the vial has been thawed after the third refreeze, it must be used. If not used after the third refreeze, do not use and discard the vial.
 - f. Each vial of CYTALUX may be penetrated only once at the time of preparation of infusion solution. Once penetrated, the vial may not be refrozen.

Updated Expiration Dates:

The expiration date of CYTALUX was extended to 48 months from the date of product manufacture. Vials and Cartons of CYTALUX labeled with the expiration date of 31 Jan 2026 and 28 Feb 2026 may remain in use for an additional 12 months beyond the labeled date if the labeled storage conditions are maintained. New expiration dates for the following lots available in the U.S. Market is as follows:

Lot Number	Printed Expiration Date on Vial and Cartons	New Expiration Date
87532A	31 Jan 2026	31 Jan 2027
87533A	28 Feb 2026	28 Feb 2027

Please keep this letter with current CYTALUX stock as a reference to the updated preparation and storage instructions and extended expiration dates.

Reporting Adverse Events:


Health care providers are encouraged to report all adverse events when using CYTALUX to On Target Laboratories at 1-844-434-9333 and to the FDA at www.fda.gov/medwatch, or by calling 1-800-FDA-1088.

Healthcare providers should direct questions on CYTALUX to On Target Laboratories at 1-844-434-9333 or cytaluxhcp.com.

For additional information about CYTALUX, including the full Prescribing Information, please visit cytaluxhcp.com.

Please refer to the enclosed full prescribing information.

Signed by:

 Sincerely,

Signer Name: Catherine Brisson
Signing Reason: I approve this document
Signing Time: 7/29/2025 | 1:38:51 PM PDT

E119DE58B2F644F6A58813DD3DA1D1C3

Catherine Brisson, PhD
Vice President, Regulatory Affairs and Quality
On Target Laboratories, Inc.
cbrisson@ontargetlabs.com
Medical Information (MI) Call Center: 1-844-434-9333

Enclosure(s): CYTALUX Full Prescribing Information