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# Cayston® (aztreonam for inhalation solution) Storage and Stability

This document is in response to your request for extended storage and stability information of Aztreonam® (aztreonam [AZLI]) 75 mg for inhalation solution and does not intend to offer an opinion regarding the clinical relevance of these data or the advisability of storing or administering any drug in a manner inconsistent with its approved labeling. Cayston® (AZLI) should be stored according to the product label.

**The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/respiratory/cayston/cayston_pi.**

## Product Labeling[1]

AZLI vials and diluent ampules should be stored in the refrigerator at 2°C to 8°C (36–46°F) until needed. Once removed from the refrigerator, AZLI and diluent may be stored at room temperature (up to 25°C [77°F]) for ≤28 days. Do not separate the AZLI vials from the diluent ampules. AZLI should be protected from light.

Do not use AZLI if it has been stored at room temperature for >28 days. Do not use AZLI beyond the expiration date stamped on the vial. Do not use diluent beyond the expiration date embossed on the ampule.

AZLI should be used immediately upon reconstitution. Do not reconstitute >1 dose at a time.

Do not use diluent or reconstituted AZLI if it is cloudy or if there are particles in the solution.

## Formulation Description

Each kit for a 28-day course of AZLI contains 84 sterile vials of AZLI and 88 ampules of sterile diluent packed in 2 cartons, each carton containing a 14-day supply. The 4 additional diluent ampules are provided in case of spillage.

## Alternative Storage and Stability Information[2]

The table below summarizes available data from in-house studies regarding the storage of AZLI for inhalation solution in varying conditions. The “acceptable duration” refers to the stability of AZLI for inhalation solution in the specified packaging and storage condition, but it does not endorse alternative packaging or use beyond the expiration date stated on the original packaging.

**Table 1. Summary of Extended Stability Data for AZLI for Inhalation Solution[2]**

| Storage Condition | Package Type | Acceptable Duration |
|---|---|---|
| -20°C to 1°C (-4°F to 33.8°F) | AZLI kit (lyophilized AZLI 75 mg vial and diluent ampule) | <30 days |
| 9–25°C (48.2–77°F) | AZLI kit (lyophilized AZLI 75 mg vial and diluent ampule) | <28 days |

| Storage Condition | Package Type | Acceptable Duration |
|---|---|---|
| 9–14°C (48.2–57.2°F) | Diluent for AZLI (0.17% sodium chloride ampule) | <24 months |
| 31–40°C (87.8–104°F) | Diluent for AZLI (0.17% sodium chloride ampule) | <6 months |

# References

1. Enclosed. Gilead Sciences Inc, CAYSTON® (aztreonam for inhalation solution). US Prescribing Information. Foster City, CA.
2. Gilead Sciences Inc. Data on File.

## Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Cayston US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/respiratory/cayston/cayston_pi.

## Follow Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

## Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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