ZYNLONTA® (loncastuximab tesirine-lpyl) – Temperature Excursion Data

Summary

- ADC Therapeutics has not conducted any studies evaluating acceptable temperature excursion data for reconstituted or diluted ZYNLONTA.
- Temperature excursion studies with lyophilized ZYNLONTA powder revealed no changes in physical or chemical properties following 48 hours of storage at a temperature range of -20°C to 40°C (-4°F to 104°F) for up to 48 hours.[1,2]
- In a temperature cycling stability study conducted by ADC Therapeutics, loncastuximab tesirine-lpyl lyophilized powder underwent three rounds of temperature cycling.[5]
    - All results met the long-term intended specifications, and it was determined that loncastuximab tesirine-lpyl lyophilized powder remains stable after 3 temperature cycles between -20°C and 40°C.
- A shipping performance verification study of the EFP 72-hour thermal shipper 625125 revealed the shipper can maintain the desired product temperature (2°C to 8°C) for 72 hours using its summer pack out configuration, and 96 hours in its winter configuration, if respective packing instructions are adhered to, including proper pre-conditioning of the phase change (gel packs) material. **Please note the product, ZYNLONTA, was not used in this study**.[7]
- ADC Therapeutics does not recommend any practices, procedures, or storage conditions that are not aligned with the ZYNLONTA product labeling and are not approved by the US Food and Drug Administration. The information provided in this document is outside of the approved storage recommendations as per the label. Please defer to your clinical judgement regarding use of the product.
- Do not use ZYNLONTA beyond the expiration date shown on the carton.[3]

Stability of Reconstituted or Diluted Product

- ADC Therapeutics has not conducted any studies evaluating acceptable temperature excursion data for reconstituted or diluted ZYNLONTA.
- Use reconstituted ZYNLONTA immediately. If not used immediately, store the reconstituted solution in the vial for up to 4 hours refrigerated at 2°C to 8°C (36°F to 46°F) or room temperature 20°C to 25°C (68°F to 77°F). Do not freeze. Discard unused vial after reconstitution if the recommended storage time is exceeded.[3]
- After dilution, if not used immediately, store the diluted ZYNLONTA infusion solution refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours or at room temperature 20°C to 25°C (68°F to 77°F) for up to 8 hours. Discard diluted infusion bag if storage time exceeds these limits. Do not freeze.[3]
- Please follow proper aseptic technique and align with local or institutional polices for compounding sterile preparations as highlighted by the American Society of Health-System Pharmacists (ASHP).[4]

Temperature Cycling

- In a temperature cycling stability study conducted by ADC Therapeutics, loncastuximab tesirine-lpyl lyophilized powder underwent three rounds of temperature cycling, from -20°C ± 5°C to 40°C ± 2°C/75 ± 5% relative humidity.[5]
    - Samples were exposed to the high and low temperatures for two days at each cycle and subsequently tested.
    - At the conclusion of the study, all results met the long-term intended specifications, and it was determined that loncastuximab tesirine-lpyl lyophilized powder remains stable after 3 temperature cycles between -20°C and 40°C.[5,6]
- Store refrigerated ZYNLONTA at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not use ZYNLONTA beyond the expiration date shown on the carton. Do not freeze. Do not shake.[3]

Shipping Performance Verification

- A shipping performance verification study was conducted to assess shipping of loncastuximab tesirine product similar, placebo vials. The study was designed to analyze the ability of the packaging to maintain physical integrity and temperature of the test material. This study was not intended to evaluate the integrity of loncastuximab tesirine product under these conditions. **Please note the product, ZYNLONTA, was not used in this study.**[7]
    - The test material used in the study did not contain active pharmaceutical ingredient.
    - The product similar vials and cartons were representative of the actual finished goods in size, weight, composition, and thermal character.
    - EFP, 48-hour thermal insulated shipper and EFP 72-hour thermal insulated shipper, Model 625125 were used.
    - The finished goods cartons, the vial, the package insert, and the tamper evident seals on the box were inspected to assess the physical integrity following ISTA-3A physical testing.
    - The performance verification study of the EFP 72-hour thermal shipper 625125 revealed the shipper can maintain the desired product temperature (2°C to 8°C) for 72 hours using its summer pack out configuration, and 96 hours in its winter configuration, if respective packing instructions are adhered to, including proper pre-conditioning of the phase change (gel packs) material.

Storage and Temperature Excursions

- Temperature excursion studies with lyophilized ZYNLONTA powder revealed no changes in physical or chemical properties following 48 hours of storage at a temperature range of -20°C to 40°C (-4°F to 104°F) for up to 48 hours.[1,2]
- A shipping performance verification study of the EFP 72-hour thermal shipper 625125 revealed the shipper can maintain the desired product temperature (2°C to 8°C) for 72 hours using its summer pack out configuration, and 96 hours in its winter configuration, if respective packing instructions are adhered to, including proper pre-conditioning of the phase change (gel packs) material. **Please note the product, ZYNLONTA, was not used in this study**.[7]

- ADC Therapeutics does not recommend any practices, procedures, or storage conditions that are not aligned with the ZYNLONTA product labeling and are not approved by the US Food and Drug Administration. Please defer to your clinical judgement regarding use of the product.

Literature Search

- A PubMed biomedical literature search conducted on July 24, 2025, yielded no further information regarding temperature excursion data associated with ZYNLONTA.

References

[1] Data on File, Time Out of Environment Memo. ADC Therapeutics.
[2] Data on File, Allowable Temperature Excursions Memo. ADC Therapeutics.
[3] ZYNLONTA® (loncastuximab tesirine-lpyl) for injection Prescribing Information, October 2022.
[4] American Society of Health-system Pharmacists. ASHP guidelines on compounding sterile preparations. Am J Health Syst Pharm. 2014;71(2):145-166. doi:10.2146/sp140001.
[5] Data on File, Temperature Cycling Memo. ADC Therapeutics.
[6] Data on File, Final Temperature Cycling Summary Report for ADCT-402 Formulation 2 Lyophilized Powder Drug Product PPQ Lot S19G022. ADC Therapeutics.
[7] Data on File, Finished Goods 48 and 72-hour Shippers, eQ12 and 625125, Performance Verification Final Report. ADC Therapeutics.

ADC Therapeutics encourages all health care professionals to report any adverse events and product quality complaints to medical information at 855-690-0340. Please consult the ZYNLONTA Prescribing Information.